

Streamlined submission process project

Progress to date

Item	Batch										
	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11
Pre-submission planning forms											
Date processing PPFs commenced	1-Nov-10	1-Dec-10	1-Jan-11	1-Feb-11	1-Mar-11	1-Apr-11	1-May-11	1-Jun-11	1-Jul-11	1-Aug-11	1-Sep-11
PPFs received by processing date	28	34	24	25	27	33	28	29	35	26	33
S. 31 response—sponsor nominated 60 day	46%	68%	38%	48%	52%	61%	61%	69%	71%	77%	46%
Assessment status											
Number not complete	5	3	2	1	0	0	1	0	0	pending	pending
Number withdrawn or deferred	n/a	1	1	3	0	0	0	0	1	pending	pending
Deficiencies (48 hours to address)	n/a	4	3	6	8	8	2	8	9	8	pending
Progress to planning letter	23	30	21	21	27	33	27	29	34	pending	pending
Application types											
New entity – A	2	4	3	2	2	2	0	3	0	1	4
New fixed dose combination – B	0	1	1	1	0	0	0	0	1	1	1
Extension of indication – C	10	2	3	0	2	1	6	3	3	1	0
Generic – D	8	12	8	11	9	20	15	11	15	11	16
Minor variation – J, G, H	4	11	5	7	12	6	7	8	13	9	9
Major variation – F	3	2	1	4	2	4	0	3	3	3	3
(multiple application types)	2 with 3	2 with 2	3 with 2	-	-	-	-	1 with 2	-	-	-
M1—Outcome of pre-submission sent											
M1 target date	15-Dec-10	15-Jan-11	15-Feb-11	15-Mar-11	15-Apr-11	15-May-11	15-Jun-11	15-Jul-11	15-Aug-11	15-Sep-11	15-Oct-11
Number met target date	23	30	21	4	18	33	0	0	0	pending	pending

Batch											
Item	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11
M2—Outcome of submission consideration sent											
M2 target date	31-Jan-10	28-Feb-11	31-Mar-11	30 Apr 11d	31-May-11	30-Jun-11	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11
Number withdrawn	-	3	1 ^a	0	0	1	2	0	pending	pending	pending
Number deferred	1	1	-	1 ^c	0	2	1	0	pending	pending	pending
Deficiencies (48 hours to address)	15	12	9 ^d	6	13	17	18	20	pending	pending	pending
Number met target date	21	11	11	20 ^d	14	0	7	10	pending	pending	pending
Number effective notification letter	21	27	20 ^b	20	27	29	23 ^b	pending	pending	pending	pending
Number not effective notification letter	1	0	1	0	0	1	2	pending	pending	pending	pending
M2 target date	31-Jan-10	28-Feb-11	31-Mar-11	30 Apr 11d	31-May-11	30-Jun-11	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11
M3—Section 31 request for information											
M3 default target date	31-May-11	30-Jun-11	31-Jul-11j	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12
Number withdrawn during evaluation	0	1	0	0	pending	pending	pending	pending	pending	pending	pending
Number with s.31 request for information	14	10	9	13	pending	pending	pending	pending	pending	pending	pending
Number with request for revised label/PI only	2	4	3	3	pending	pending	pending	pending	pending	pending	pending
Number with no requests	0	1	0	1	pending	pending	pending	pending	pending	pending	pending
Number of letters met target date	16 ^f	13	11 ^j	16	pending	pending	pending	pending	pending	pending	pending
Number of individual evaluations required	59	29	34	55	pending	pending	pending	pending	pending	pending	pending
Number of individual questions/requests	347 ^g	251	240	380	pending	pending	pending	pending	pending	pending	pending
M3 extended target date	30-Jun-11	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12
Number withdrawn during evaluation	0	0	0	pending	pending	pending	pending	pending	pending	pending	pending
Number with s.31 request for information	5	5 ^h	6	pending	pending	pending	pending	pending	pending	pending	pending
Number with request for revised label/PI only	0	1	0	pending	pending	pending	pending	pending	pending	pending	pending
Number with no requests	0	2	0	pending	pending	pending	pending	pending	pending	pending	pending

Batch											
Item	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11
Number met target date	5	6	8	pending	pending	pending	pending	pending	pending	pending	pending
Number of individual evaluations required	15	32	31	pending	pending	pending	pending	pending	pending	pending	pending
Number of individual questions/requests	235	96	216	pending	pending	pending	pending	pending	pending	pending	pending
M3 default target date	31-May-11	30-Jun-11	31-Jul-11j	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12
Number withdrawn during evaluation	0	1	0	0	pending	pending	pending	pending	pending	pending	pending
Number with s.31 request for information	14	10	9	13	pending	pending	pending	pending	pending	pending	pending
Number with request for revised label/PI only	2	4	3	3	pending	pending	pending	pending	pending	pending	pending
Number with no requests	0	1	0	1	pending	pending	pending	pending	pending	pending	pending
Number of letters met target date	16 ^f	13	11j	16	pending	pending	pending	pending	pending	pending	pending
Number of individual evaluations required	59	29	34	55	pending	pending	pending	pending	pending	pending	pending
Number of individual questions/requests	347 ^s	251	240	380	pending	pending	pending	pending	pending	pending	pending
M4—End of s. 31 response period											
M4 default date – 30 day response period	30-Jun-11	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12
Number responses expected	9	10	8	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received by due date	9	7	8	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received after due date	0	3	0	pending	pending	pending	pending	pending	pending	pending	pending
Number responses not received	0	0	0	pending	pending	pending	pending	pending	pending	pending	pending
M4 default date – 60 day response period	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12
Number responses expected	6	8	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received by due date	5	8	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received after due date	1	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses not received	0	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
M4 date where MS3+1 & 30 day response period	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12
Number responses expected	2	0	pending	pending	pending	pending	pending	pending	pending	pending	pending

Batch											
Item	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11
Number responses received by due date	2	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received after due date	0	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses not received	0	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
M4 date where MS3+1 & 60 day response period	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12	30-Jun-12
Number responses expected	3	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received by due date	2	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received after due date	1	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending
Number responses not received	0	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending
M4 default date – 30 day response period	30-Jun-11	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12
Number responses expected	9	10	8	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received by due date	9	7	8	pending	pending	pending	pending	pending	pending	pending	pending
Number responses received after due date	0	3	0	pending	pending	pending	pending	pending	pending	pending	pending
Number responses not received	0	0	0	pending	pending	pending	pending	pending	pending	pending	pending
M5—Outcome of submission consideration sent											
M5 default date – 30 day response period	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12
No. submissions for which evaluation reports required	9	7	pending	pending	pending	pending	pending	pending	pending	pending	pending
No. submissions where reports sent by due date	0	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
M5 default date – 60 day response period	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12	30-Jun-12
No. submissions for which evaluation reports required	4	8	pending	pending	pending	pending	pending	pending	pending	pending	pending
No. submissions where reports sent by due date	0	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending
M5 date where MS3+1 & 30 day response period	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12	30-Jun-12
No. submissions for which evaluation reports required	4	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
No. submissions where reports sent by due date	0	0	pending	pending	pending	pending	pending	pending	pending	pending	pending

Item	Batch										
	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11
M5 date where MS3+1 & 60 day response period	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12	30-Jun-12	31-Jul-12
No. submissions for which evaluation reports required	3	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending
No. submissions where reports sent by due date	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending
M5 default date – 30 day response period	31-Jul-11	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12
No. submissions for which evaluation reports required	9	7	pending	pending	pending	pending	pending	pending	pending	pending	pending
No. submissions where reports sent by due date	0 ⁱ	0	pending	pending	pending	pending	pending	pending	pending	pending	pending
M5 default date – 60 day response period	31-Aug-11	30-Sep-11	31-Oct-11	30-Nov-11	31-Dec-11	31-Jan-12	29-Feb-12	31-Mar-12	30-Apr-12	31-May-12	30-Jun-12
No. submissions for which evaluation reports required	4	8	pending	pending	pending	pending	pending	pending	pending	pending	pending
No. submissions where reports sent by due date	0	pending	pending	pending	pending	pending	pending	pending	pending	pending	pending

^a Includes 1 submission that was re-lodged for consideration in the February batch.

^b Includes 1 submission that was deferred from a previous batch.

^c The TGA requested one sponsor to defer lodgement of submission until December due to dependency on outcome of evaluation of another submission.

^d As notified to sponsors of February batch, notification of outcome of submission consideration would be delayed until 6 May 2011, due to Easter holidays. All notification letters were issued on 6 May 2011.

^e Extended M3 dates include submissions where milestone 3 was extended by one month due to unsecured evaluation resources or complex submissions.

^f Includes 1 submission for which the clinical evaluation was not completed in time. Consolidated s. 31 request issued for completed evaluation areas.

^g See s.31 request tables for breakdown by application type and module.

^h Consolidated s.31 request for 1 submission deferred to August 2011 due to late evaluation report

ⁱ All reports were released 2 August 2011

^j As 31 Jul 2011 fell on the weekend, the milestone date was moved to the next working day without impacting on legislated response times

Section 31 request breakdowns

Application type	Number of questions/requests for information November 2010 batch				
	Module 3	Module 4	Module 5	RMP	PI/CMI/Other
A	55	24	7	14	30
B	0	0	0	0	0
C*	14	4	16	45	11
D	155	0	13	0	63
F	19	0	0	7	0
G	0	0	0	0	0
H	0	0	0	0	0
J	0	0	0	0	4
Total number of questions/requests = 481					

* Includes submissions with multiple application types where the primary application type is extension of indication

Application type	Number of questions/requests for information December 2010 batch*				
	Module 3	Module 4	Module 5	RMP	PI/CMI/Other
A	44	0	9	9	13
B	15	0	3	0	12
C*	45	0	5	18	10
D	115	0	0	0	76
F	7	0	1	19	23
G	1	0	2	0	0
H	16	1	0	0	2
J	5	0	0	0	94
Total number of questions/requests = 545					

* Includes submissions with multiple application types where the primary application type is extension of indication

Application type	Number of questions/requests for information January 2011 batch*				
	Module 3	Module 4	Module 5	RMP	PI/CMI/Other
A	43	8	14	25	19
B	18	0	0	6	8
C*	32	0	12	30	9
D	80	0	10	0	54
F*	0	0	0	2	2
G	-	-	-	-	-
H	2	9	0	0	0
J	0	0	0	0	73
Total number of questions/requests = 456					

* Includes submissions with multiple application types where the primary application type is that stated

Application type	Number of questions/requests for information February 2011 batch#				
	Module 3	Module 4	Module 5	RMP	PI/CMI/Other
A	-	-	-	-	-
B	-	-	-	-	-
C*	-	-	-	-	-
D	149	2	6	5	124
F	10	3	11	5	5
G	-	-	-	-	-
H	-	-	-	-	-
J	13	0	6	0	41
Total number of questions/requests = 380					

* Includes submissions with multiple application types where the primary application type is that stated

Data is incomplete. Complete data will be available next edition.