

Summary Tables

MEDICAL DEVICES

CEIC Statistics (Cumulative data until 31-12-2015)

Issued Opinion (CEIC's Time)

	Type of Request									
	PP					PA				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
1 st Trim.					0					
2 nd Trim.	56,5	47	31	102	4					
3 rd Trim.	32,7	34	29	35	3					
4 rd Trim.	44,6	49	33	57	5					
Total	45,6	35	29	102	12					0

Table 1: Statistics of time (days) for issuing the final opinion by type of request.

Validation

	Type of Request									
	PP					PA				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
Total	4,5	4	1	42	26	13	13	13	13	1

Table 2: Statistics of time (days) used for validation by type of request.

Time used by the Experts

	Type of Request									
	PP					PA				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
Total	28,2	19	12	138	12					0

Table 3: Statistics of time (days) used by the experts for the evaluation of the processes by type of request.

* The zero time means that the answers were given on the same day.

Time used for Additional Requests

	Type of Request									
	PP					PA				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
Total	23,9	20	3	59	17					0

Table 4: Statistics of time (days) used by the sponsor for the clarifications on the additional information, by type of request.

Issued Opinion (Total time)

	Type of Request									
	PP					PA				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
1 st Trim.										
2 nd Trim.	76,3	62	37	145	4					
3 rd Trim.	60,0	49,0	43	88	3					
4 rd Trim.	64,4	71	37	74	5					
Total	67,3	70	37	145	12					0

Table 5: Statistics of time (days) for issuing the final opinion by type of request, including the clock stops for additional information.