

CEIC STATISTICS

(Cumulative data until 31-12-2015)

2015

MEDICAL DEVICES

Fig. 1 - Number of Submissions

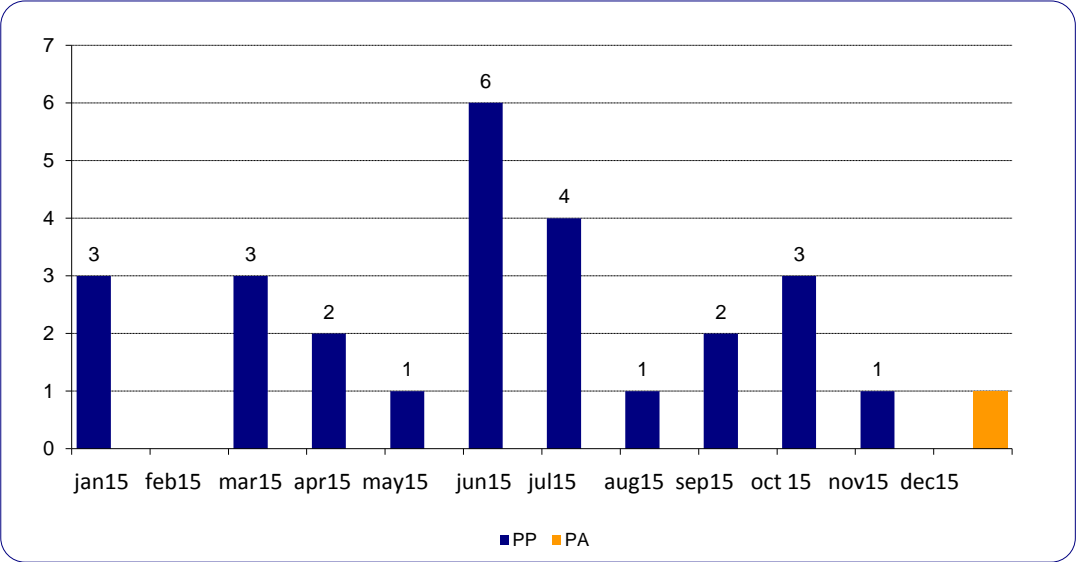


Fig. 2 - Validation

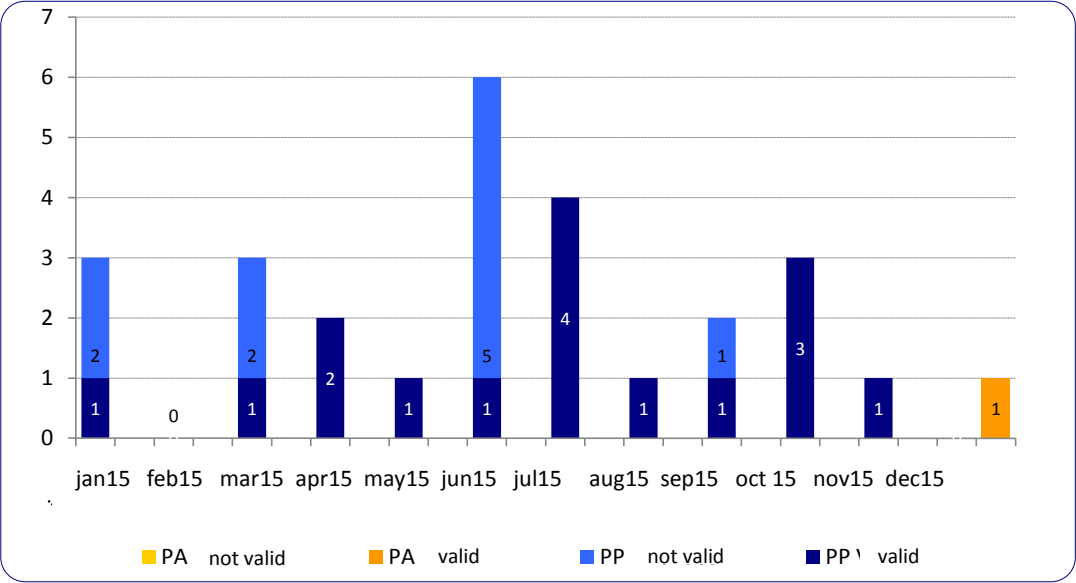


Fig. 3 - Requests for additional Information

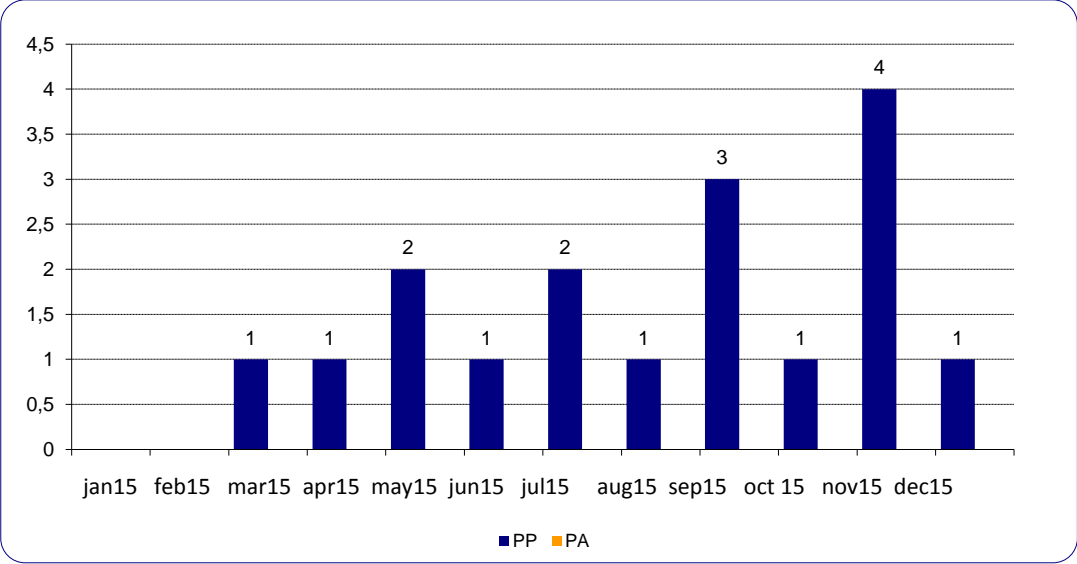


Fig. 4 - Requests for additional information (% of total)

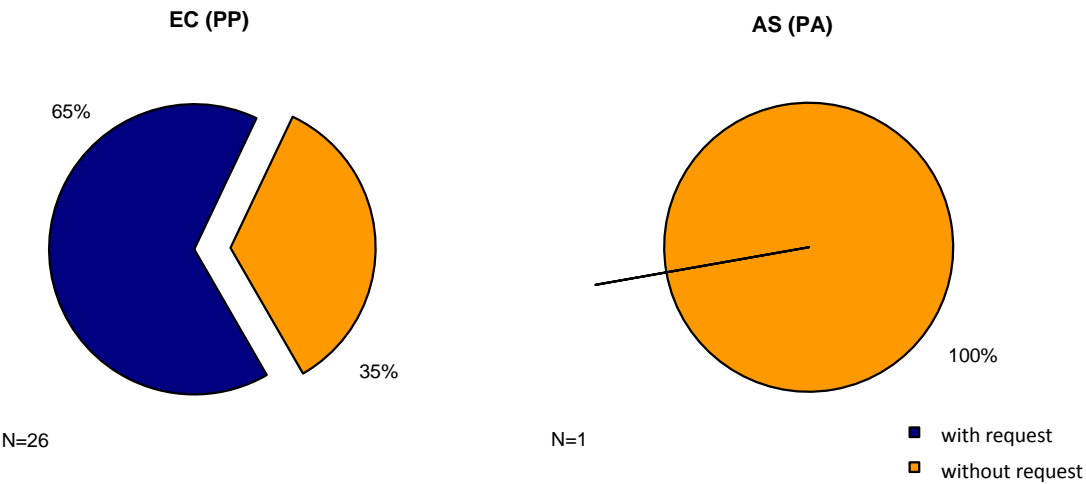


Fig. 5 - Issued Opinions

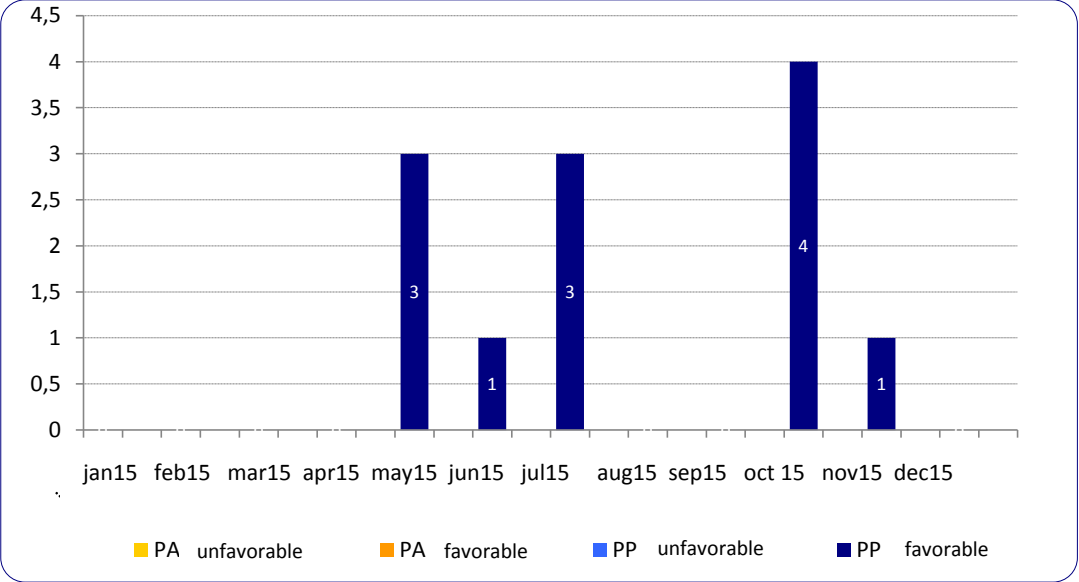


Fig. 6 - Favorable and unfavorable opinions (% of total)

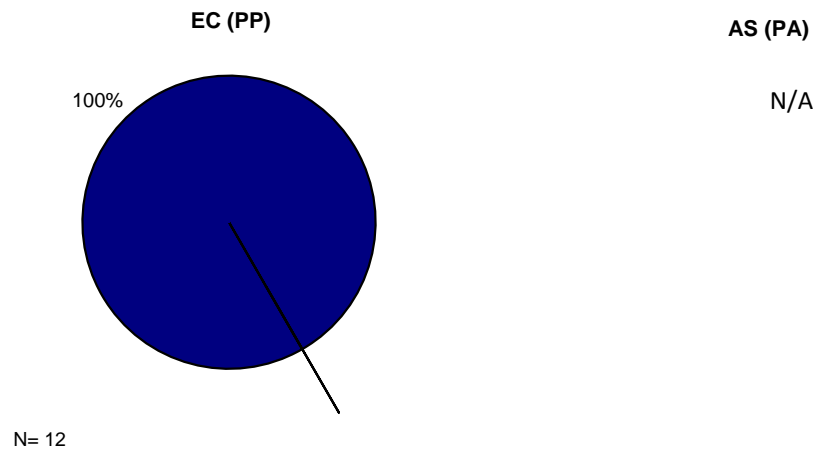


Fig. 7 - Issued Opinion (PP)

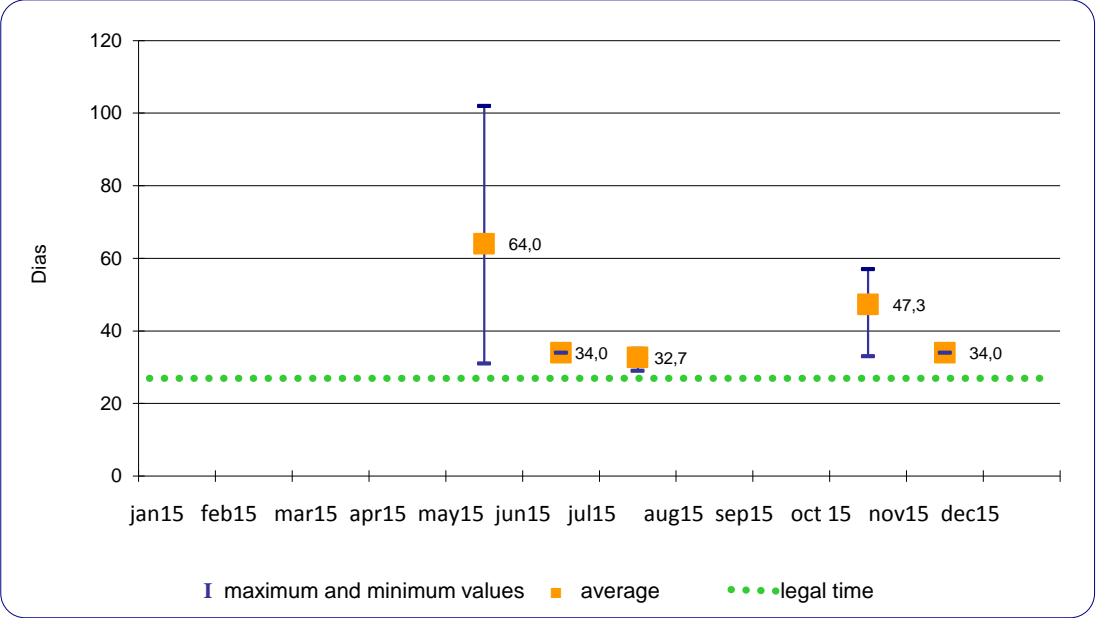


Fig. 8 - Issued Opinion (PA)

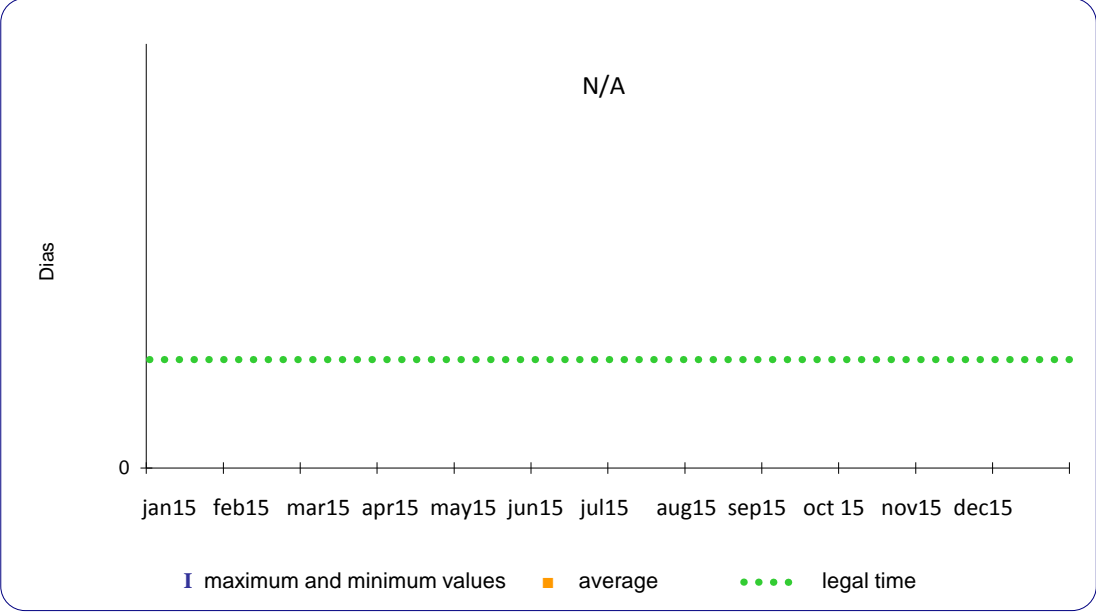


Fig. 9 - Issued opinions within and beyond the legal limit

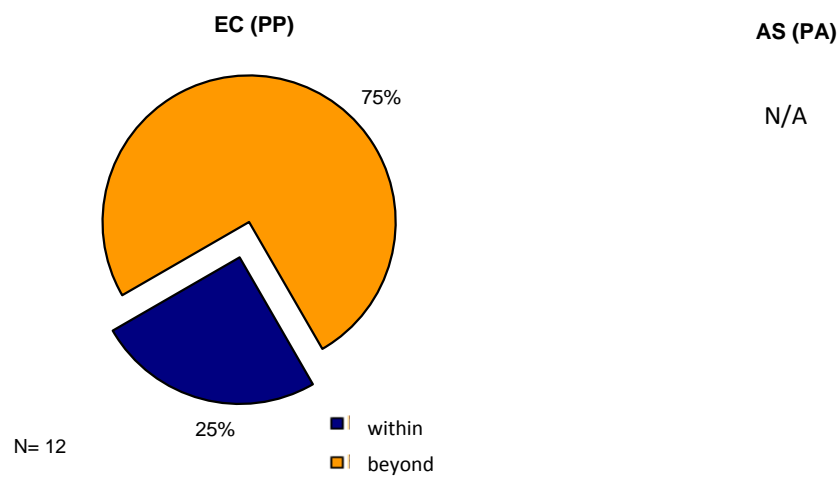


Fig. 10 - Response time of sponsor for additional information (PP)

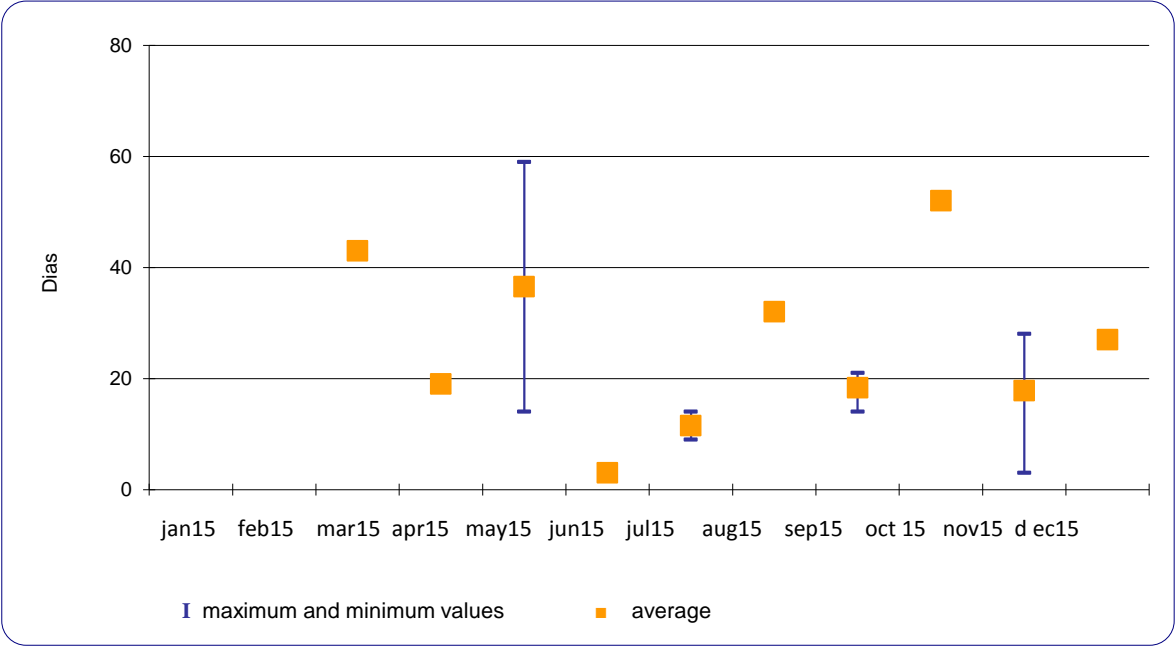


Fig. 11 - Total time for issuing of an opinion (PP)

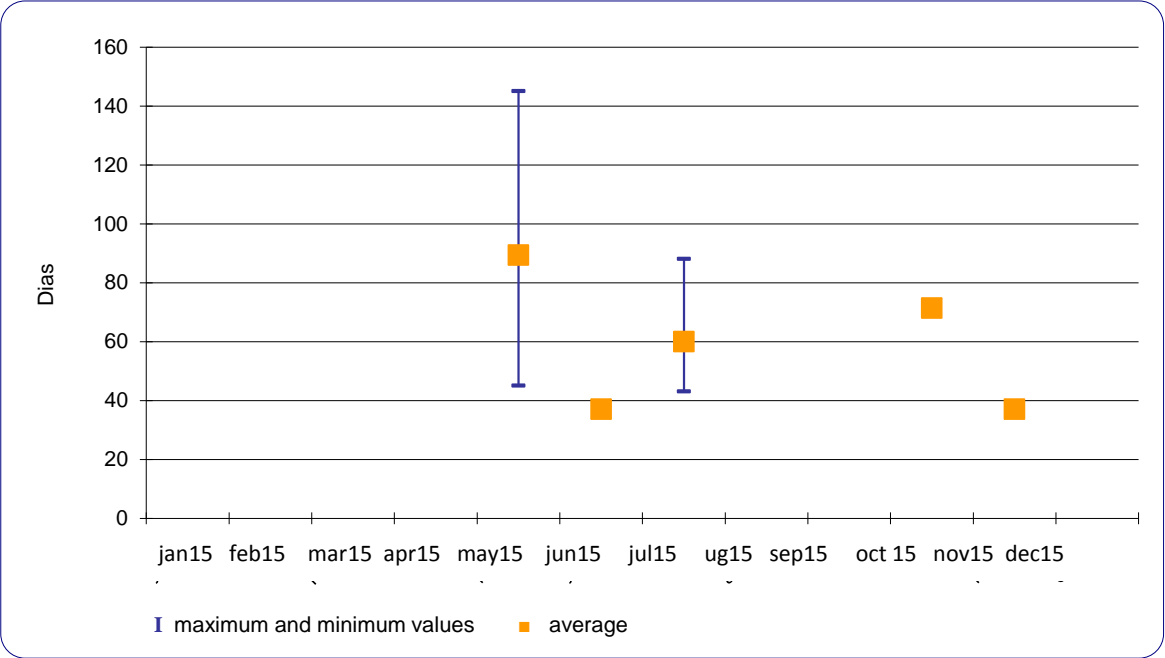
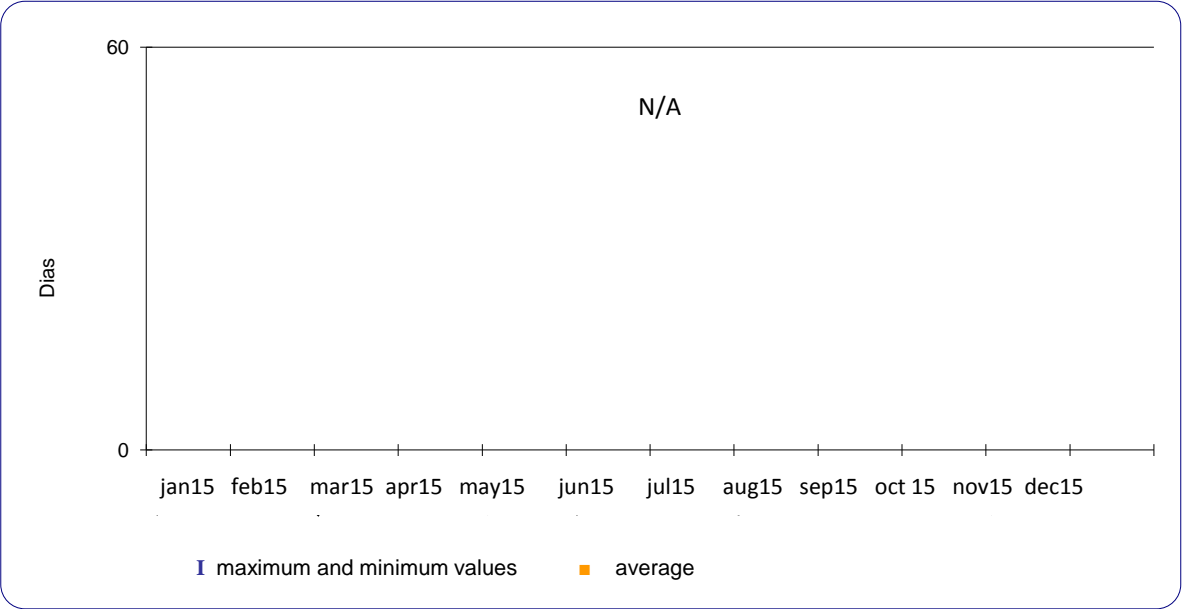
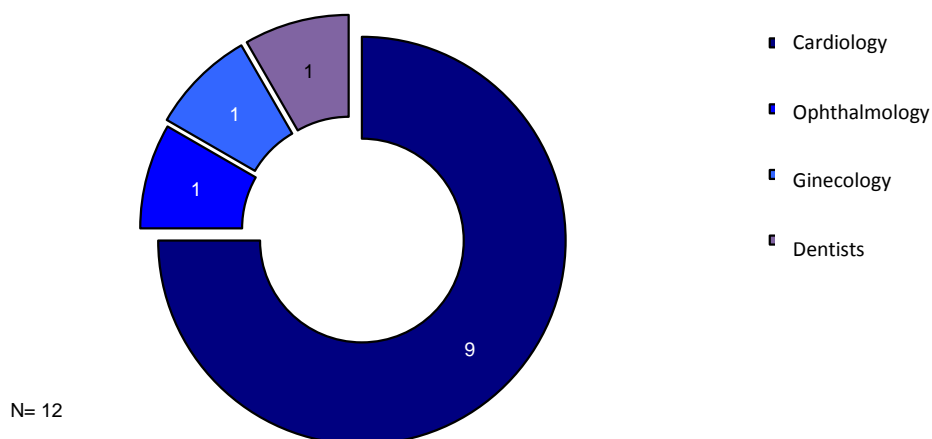


Fig. 12 - Total time for issuing of an opinion (PA)



Note: Total time for issuing of an opinion includes the time used by the sponsor to comment on the request for additional information.

Fig. 13 - Issued opinions by therapeutic area (PP)



Metodology

Total submissions were calculated considering the number of total submitted processes to CEIC during the corresponding reported period, and excluding canceled processes.

The validation statistics are related to the submitted processes during the corresponding reported period; validation may have occurred a few days after the last reported month.

Requests for additional information occur when clarification is requested from the applicant. The requests for additional information refer to the processes validated during the year 2015.

For the calculation of total opinions, all processes concluded by CEIC were considered, whose date of plenary decision falls within the period to which the report relates, irrespective of the date of submission of the applications.

The number of days to issue a final opinion by CEIC was calculated considering the period between the date of submission and the date of issuing the letter of plenary deliberation (excluding the time used by the sponsor for additional clarifications); total time for issuing an opinion includes the time used for additional clarifications.

Opinions were considered beyond the legal limit if they were issued: after 30 days for new clinical trials ; regarding substantial amendments, opinions were beyond the legal limit of 20 days .

Abbreviations:

PP - Medical Device Study

PA - Substantial amendment

CC - Medical Device Study

AS - Substantial amendment