Centralised Procedure EFPIA Analysis of Performance Indicators New Applications 2005-2006

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Questionnaire

Objective

- Examine level of satisfaction of applicants during different steps of the Centralised Procedure regarding
  - Communication, Transparency, Scientific quality

Background information

- up to 2005: 55 questions
- from 2006: 80 questions
  - Most ‘old’ 55 questions plus new questions capturing new aspects of the centralised procedure
  - e.g. conditional approval, exceptional circumstances, accelerated assessment, SAG involvement, EPAR summary, decision making process

Questionnaire instruments

- Evaluation scale
  - **strongly disagree** (0 points) -**strongly agree** (10 points)
- Open fields for comments and durations
- Yes/No questions

Reporting period

- Previous survey: **June 2004 to June 2005** (12 months)
  - 24 New Products received positive opinions, of which 20 companies responded to survey:
  - 7 applications withdrawn of which 2 companies responded
  - 0 negative opinions

2004/5

- This survey: **June 2005 to October 2006** (16 months)
  - 60 New Products received opinions, 54 not counting duplicates.
  - 42 questionnaires were completed:
    - 41 positive opinions
    - 1 negative opinion
  - 8 applications withdrawn. Questionnaires were completed for 2 of those

2005/6

- Longer reporting period to collect sufficient data on opinions after enforcement of the New Medicines Legislation (NML) - per November 2005. Where appropriate data will be provided separately for opinions obtained
  - pre-NML **June-November 2005** - 6 months (16 applications)
  - post-NML **December 2005- October 2006** - 10 months (28 applications)

2005

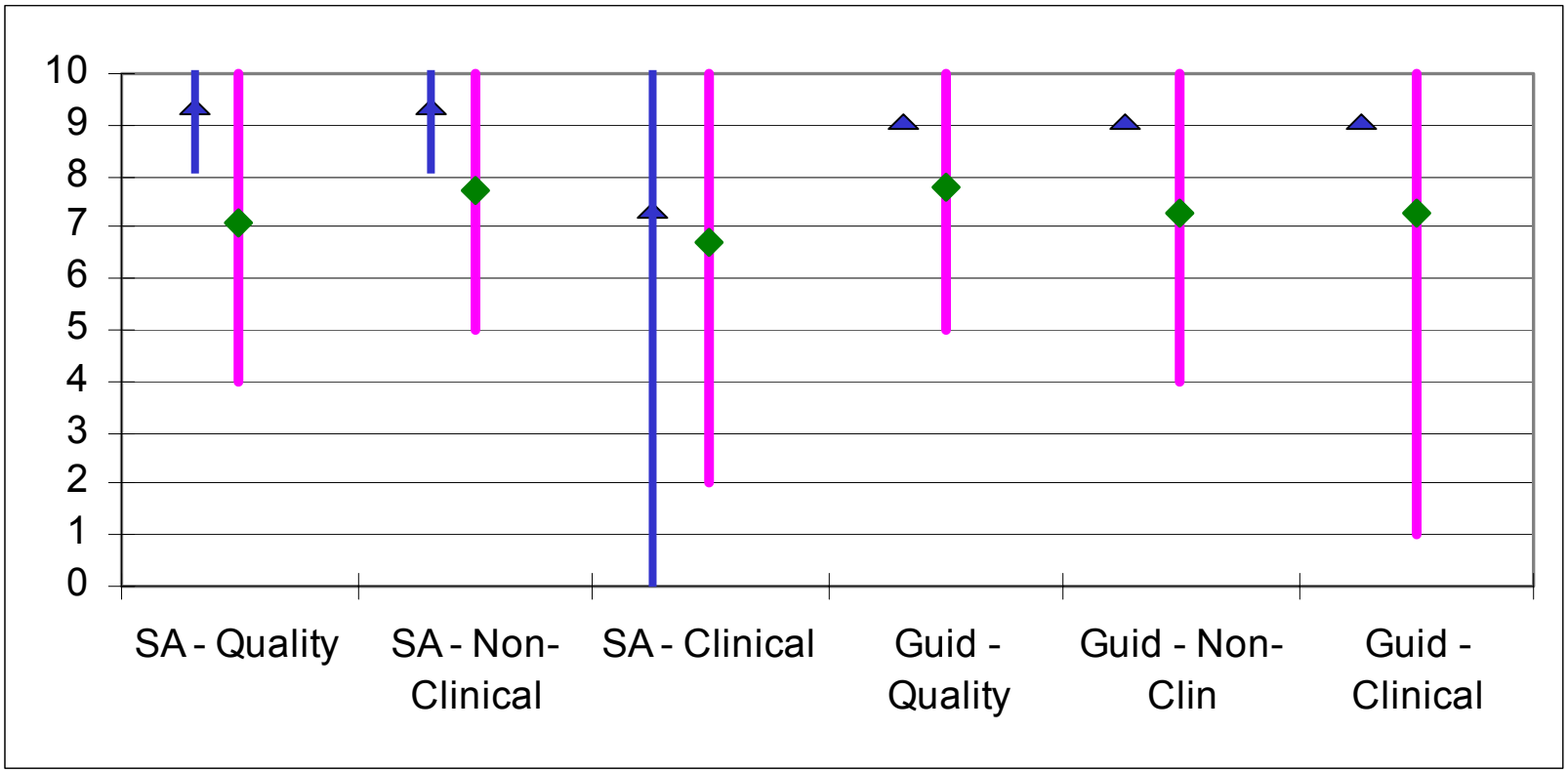
2006

Pre-submission phase: Scientific Advice (SA)

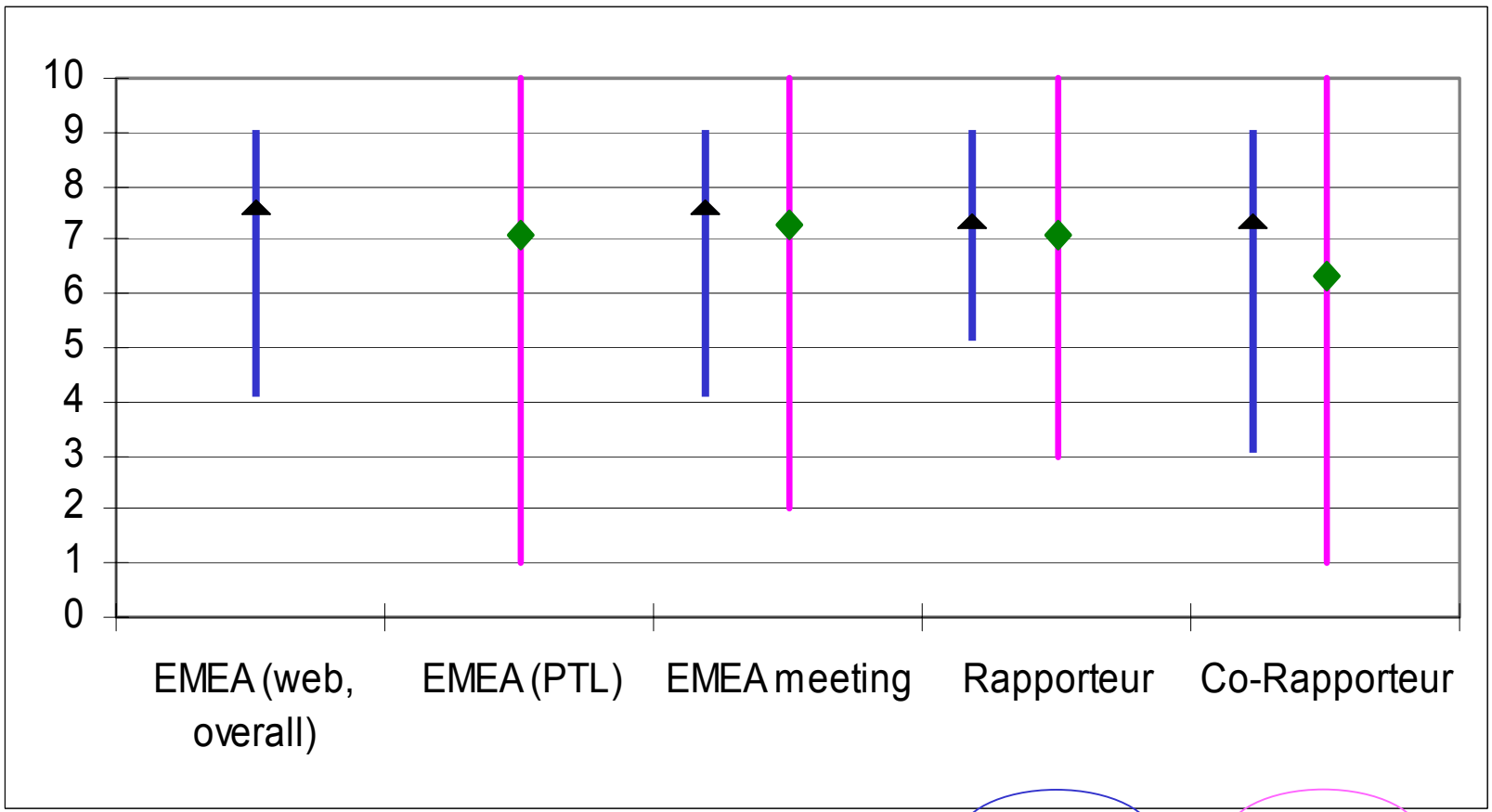
	National SA	CHMP SA	No SA
2004/5		30%	
2005	56%	19%	38%
2006	61%	43%	21%
2005/6		34%	

- No experiences with parallel SA reported
- Conditional approval and Exceptional Circumstances have not been common SA discussion topics (2 and 3 applications respectively in 2005/6)

Assessment Compliance with Scientific Advice and CHMP guidelines



Pre-submission phase: Quality of Guidance



Pre-submission phase: Accelerated Assessment (AA),

Conditional approval, Exceptional Circumstances

AA	Requested	Granted
2005	44%	12.5%
2006	26%	0
2005/6	33%	5%

- 2/43 applications granted AA
- No accelerated review granted for post-NML opinions
  - From CHMP's meeting reports: 2/11 requests have been granted AA from 12/05 to 11/06
- No company requested conditional approval and 3 requested approval under exceptional circumstances

Day 0
Validation

- Baseline score for EMEA support during this period is 7.8 (range: 4-10)

Day 70/80
Quality of Assessment documents

- Initial Assessment Reports (AR):

	Rapporteur			**Co-Rapporteur**		
	Q	NC	Clinical	Q	NC	Clinical
2004/5	7.6-7.8	7.7-8.0	7.6-7.9	7.4-7.6	7.4-7.7	7.3-7.6
2005/6	7.7-7.9	7.9-8.0	7.7-7.8	7.1-7.5	7.3-7.5	6.8-7.0

- Big drop in scores for all 3 Co-Rapporteur ARs in 2005, with some recovery in 2006
- Drop in scores for Co-Rapporteur Clinical AR in 2005/6

Day 120
Joint AR and List of Questions (LoQ)

- No change in marks for Joint AR, LoQ, and CHMP comments on product information from 2004/5 survey
  - All within 7-8 range
- Number of Applicants that met with (Co)Rapporteur on LoQ increased ....
  - from 60% to 77%

  ...but the provided guidance was rated lower
  - from 8.3 to 7.3
- QRD comments on product information were less clear (6.9-7.4) than CHMP ones (7.4-7.8) ....

  ...but the few applicants that met with QRD (14%)

  ...rated the meeting as very useful (7.4-8.5)

Day 150-180 Response AR and List of Outstanding Issues (LoOI)

- No change in marks for Response to AR
  - range: 7.6-8.1
- 23% felt that CHMP raised issues at time of LoOI that were not previously mentioned during review (up from 10%)
- The guidance during this period received similar marks as during last survey
  - EMEA guidance was rated 7.6
  - (Co)Rapporteur guidance was rated 7.9
- For 59% of the applications there has been a meeting with the (co)rapporteur at this stage

Day 181
Oral Explanation (OE)

- An OE took place for 39% of applications
  - several additional OEs were scheduled but got cancelled (late)
  - In 2004/5 survey mentioning of just 2 OEs (10%)
- Marks for interactiveness and scientific quality rather low

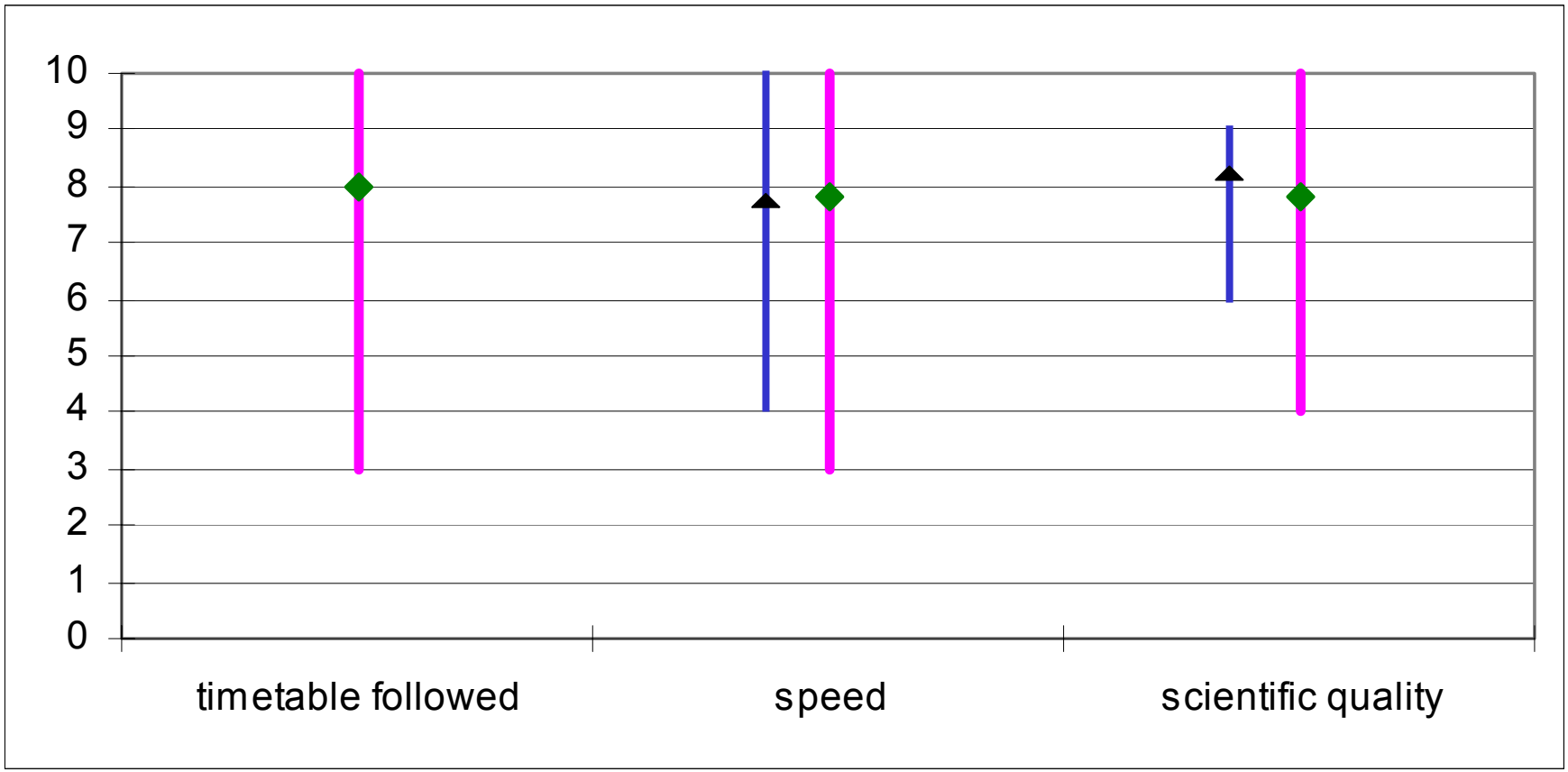
	2004/5	2005/6
Preparation sufficient	6.5	7.5
Interactive	7.5	5.7
Scientific quality	7.5	5.7
Information post-OE	8.5	7.1

SAG/WP/expert group involvement

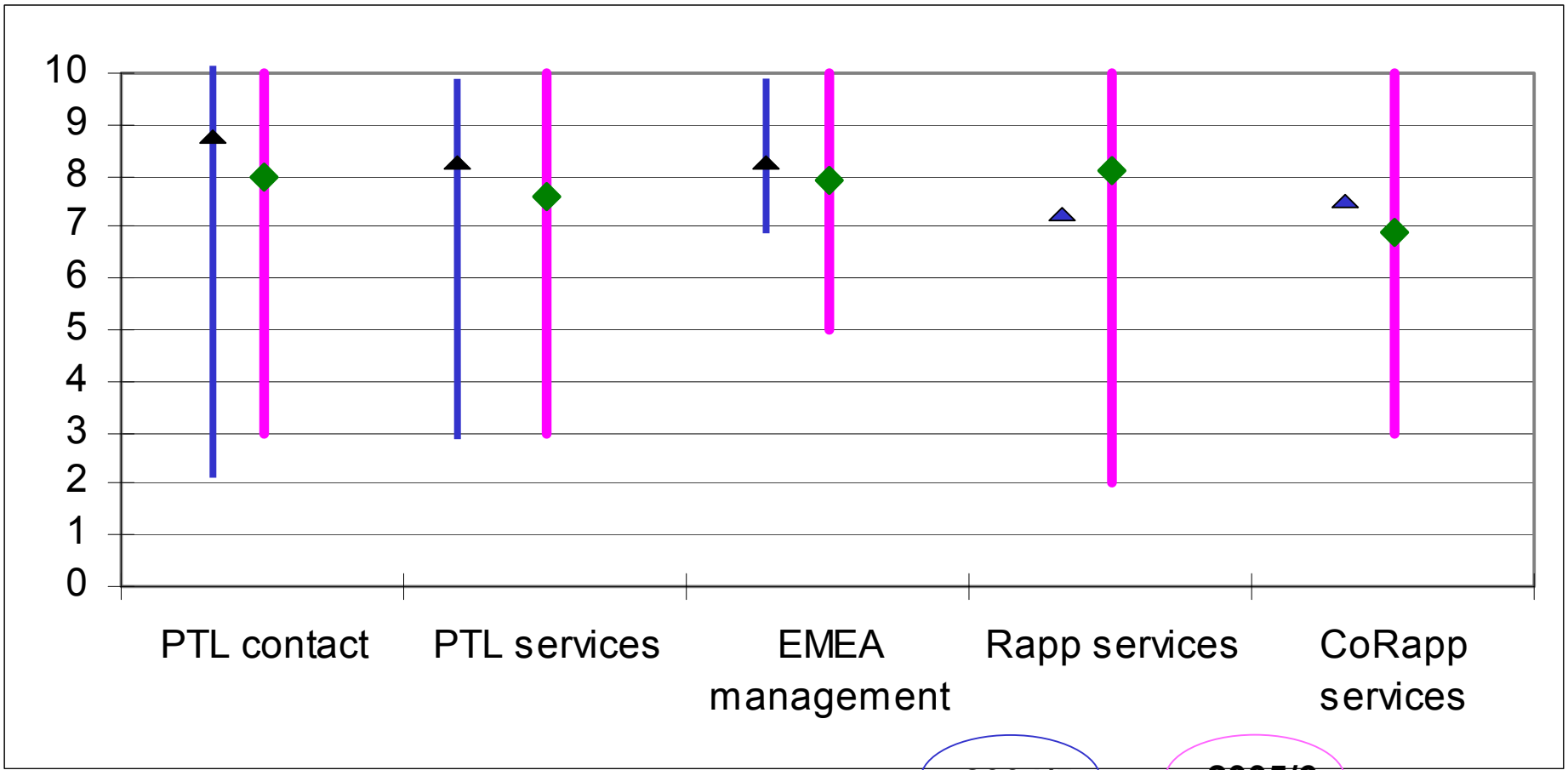
- A SAG was involved in 7 applications and a WP or other expert group in 6
- Marks for applicant participation and scientific quality leave room for improvement

		2005/6
Preparation sufficient		7.1
Applicant participation		5.8
Scientific quality		6.7

Day 1-210
Overall Assessment

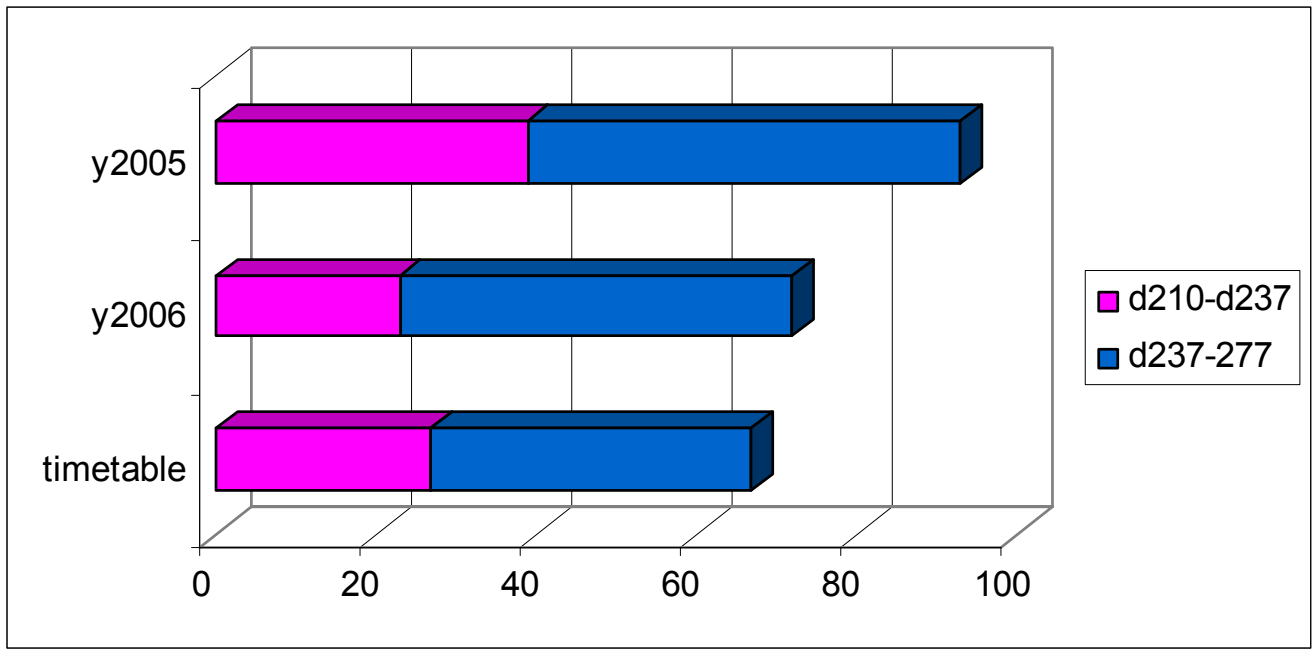


Day 1-210
Interaction with EMEA and (co)rapporteur



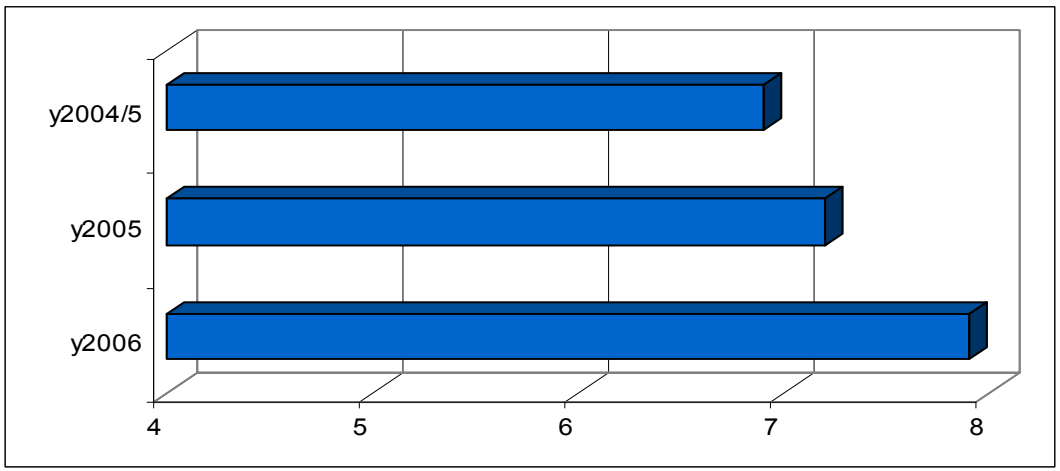
Day 210-277
Decision making process

- Graph below reflects responses on duration of two steps, together covering the whole decision making process
  - Day 210-237: CHMP opinion to transfer of it to EC
  - Day 237-277: transfer of opinion till Decision
- Both steps faster in 2006, reflecting implementation of new legislation!



Day 210-277

- However satisfaction with step 2 > step 1
  - Step 1:satisfaction with the way agencies handled the translation phase is not high (6.4) and QRD comments were often late (5.5)
    - In free text many examples of late comments
    - More appreciation for EMEA's support during this step similar to the 2004/5 result: 7.2 v 7.0
  - Step 2: Satisfaction increases with decreasing duration (see below)
    - satisfaction with EC management up from 7.25 (2005) to 8.0 (2006)



Post-Decision Phase

- EPARs:
  - Clarity
    - similar scores for quality and clinical: 7.1-7.4
    - Slight drop in scores for non-clinical: 7.9 vs 7.3
  - More satisfaction with Confidentiality aspects: 7.6-7.9 vs 6.9-7.1
  - 66% felt there had been sufficient opportunity to comment, although initial quality varied.
- EPARs published 35 days after Decision
  - range 3-220
- EPAR summary for the public:
  - Clarity rated 7.1
- EMEA support for management of Follow Up Measures/Specific Obligations: 6.7

Conclusions

- High productivity in 2005/6 (opinions, OEs)

- Marked decrease in perceived compliance of actual assessment with recommendations in guidelines*

- Formalisation of accelerated review has not resulted in an increased use of this provision

- Less satisfaction with services of Co-Rapporteur*; increased appreciation for Rapporteur*

- Scientific quality and interactiveness of OE* and of SAG/expert group interactions not high; overall scientific quality rated lower as well

* previous survey showed opposite trend

Conclusions (ii)

- More interaction with (co)rapporteur around day 120, but level of guidance rated lower

- QRD comments not always clear and sometimes inconsistent; more meetings with QRD might help increase understanding

- Increased satisfaction with the treatment of confidential information for inclusion in the EPAR

- Further reduction in duration of decision making process, more satisfaction with Commission‘s management of it, but dissatisfaction with (some) agencies and late QRD comments