Centralised Procedure: EFPIA Analysis of Performance Indicators Extension of Indications 2005-2006

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Centralised Applications Performance Indicators

- Type II variations for new indications
- 48 procedures (8 duplicates) finalised between June 2005 - September 2006 (28 procedures in 2004-2005)
- 3 applications withdrawn
- 32 responses received in total including 30 positive outcomes and 2 withdrawals (18 responses in 2005)
- 31% national Scientific Advice (SA); 19% CHMP SA ; 69% No SA. Only 6/16 requested SA were followed

	National	EMEA
• Yes :	10	6
• No :	20	23

Centralised Applications Performance Indicators

- Key results focus on
  - **Information/Guidance provided to applicants**
  - Interactions with (Co) Rapporteurs and Product Team Leaders (PTLs)
  - Quality of scientific discussion in the Assessment Report (AR)
  - Adequacy of the European Public Assessment Reports (EPARs)

Pre-Submission Guidance from EMEA PTL, meeting, (Co)-Rapporteur (Q9-12)

- Adequacy of pre-submission guidance:
  - from PTL: 7.5 (range 5-10)
  - from meeting with EMEA staff: 7.5 (range 5-10)
  - from Rapporteur: 7.6 (range 5-10)
  - from Co-Rapporteur: 7.5 (range 5-10)

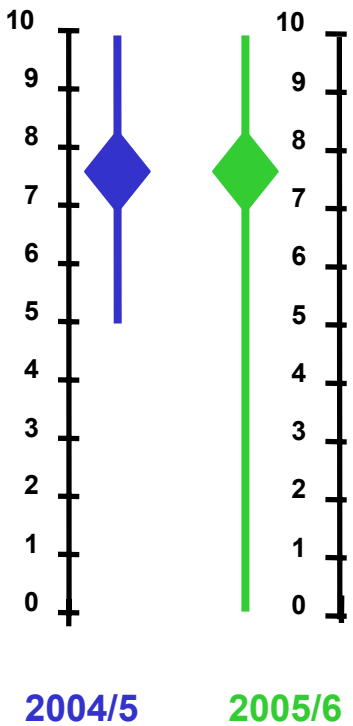
  [Pre-submission guidance by EMEA (web-site, staff) and Rapporteur during 2004/5: 7 (range 5-8)]

- Pre-submission guidance provided by EMEA (web-site, staff) and Rapporteur, when applicable, more satisfying compared to last year
- Pre-submission guidance provided by Co-Rapporteur also favourable

Pre-Submission Guidance from EMEA PTL, meeting, (Co)-Rapporteur (Q9-12)

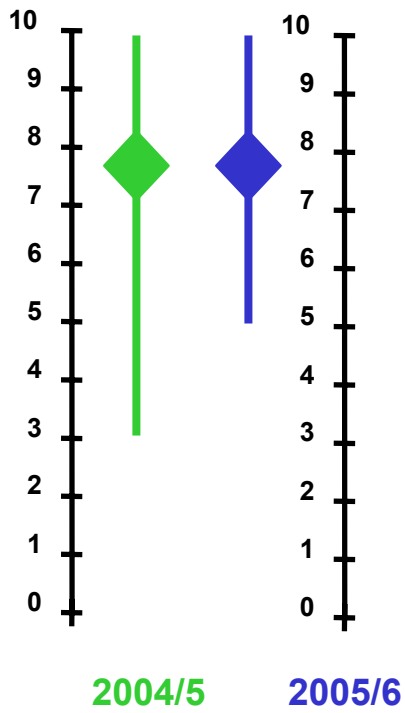
- Some comments :
  - ‘Pre-submission guidance was appropriate and helpful’
  - ‘The advice given by the Rapporteur at the time of national scientific advice was different from the one we received at the pre-submission meeting. Based on the feed-back from the pre-submission meting, we had to significantly postpone the submission to include 1 year of safety and efficacy data.”

Guidance from Product Team Leader (Q60)



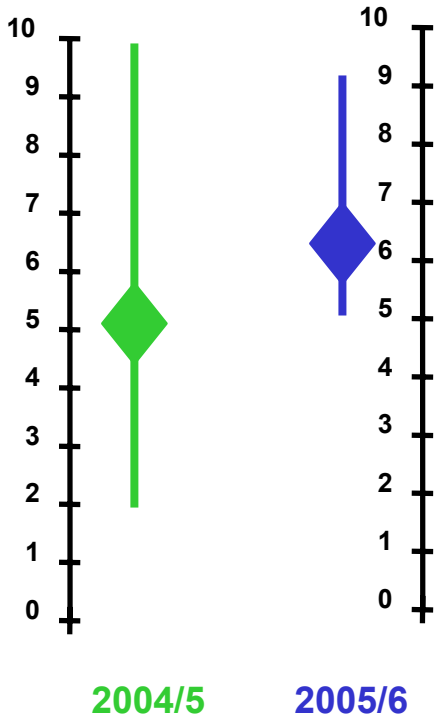
- Interaction and advice from PTL, in terms of level of communication, transparency, guidance, management of the overall process, were generally good, although more variability was observed compared to previous year
- Some comments:
  - 'We were satisfied with the level of communication, transparency and guidance from the medical assessor (Rapporteur) and the EMEA product leader as this helped in getting a CHMP positive opinion smoothly."
  - 'During this procedure four different EMEA PTLs were assigned, two of whom were excellent but also one who was extremely difficult to contact."
  - 'EMEA Product Team Leader not willing to share other CHMP Members comments, even if they had impact on procedure timelines. Other Team leaders at the EMEA had a different approach. More transparency and consistency would be welcome'

Guidance from Rapporteur (Q61)



- Satisfaction with quality of guidance, in terms of the level of communication, transparency, guidance through the process and debriefing from the Rapporteur, was very similar to last year, and feedback received was consistently more positive

LoOI guidance from (Co)-Rapporteur team(s) (Q43)



- Definite improvement in guidance and debriefing from the (Co)-Rapporteur team(s) compared to last year, and less variability
- Mean score still fairly low and could be improved

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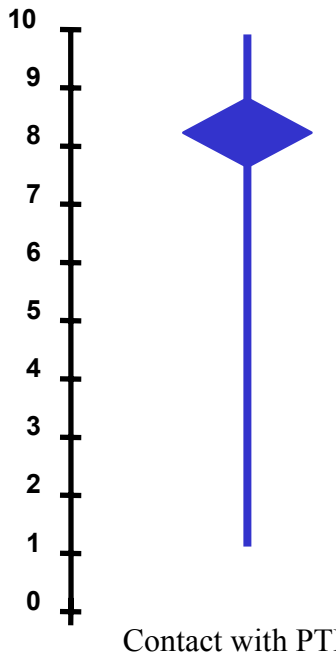
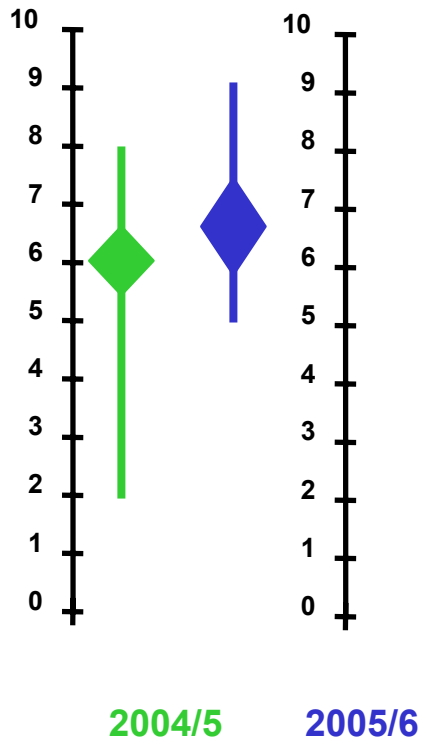
Contact with PTL (Q59)



2005/6

- High variability in ease of contact with PTL, but mean score was high
- Previous year's comment:
  - 'Ease of contact with the PTL during summer holidays should be improved'
- One comment:
  - 'PTL partially on holiday at the time of our responses to the 1st request for supplementary information where her input was necessary; replacement was disappointing in her input'

Communication with Co-Rapporteur (Q62)



- When there was a Co-Rapporteur, communication was better than previous year, with much less variability in response scores
- One comment:
  - 'We have had no relationship with co-rapporteur for this dossier with the exception of the pre-submission meeting. Throughout the procedure, feed-back came from PTL and Rapporteur when needed.'

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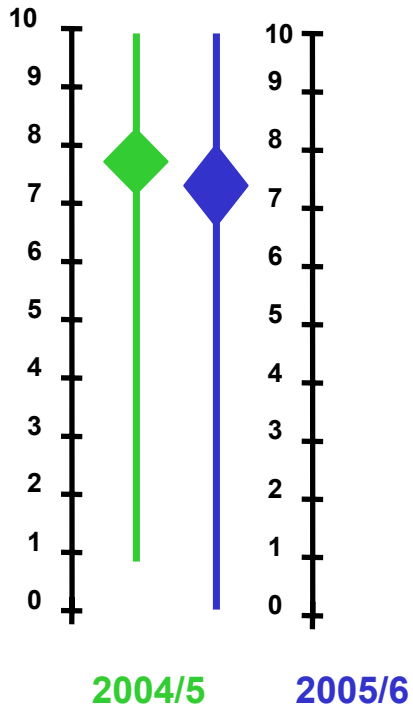
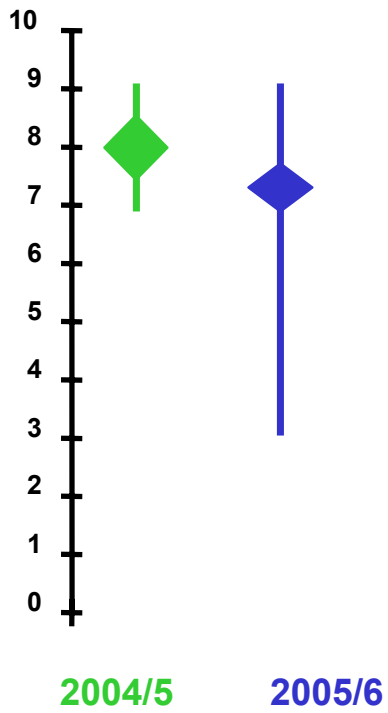
Rapporteur's Assessment Report (Q21)



- Almost similar quality of scientific discussion in the clinical section of the Rapporteur's Assessment Report compared to previous year
- Some comments:
  - 'The Rapporteur's overall conclusion and benefit/risk assessment was clear'
  - 'Clinical efficacy statements were deleted in the proposed SPC text without any scientific rationale other than 'this information is not considered necessary''.

Discussion in CHMP Assessment Report (Q27)



- Appears to be lower level of satisfaction with the quality of scientific discussion in the clinical section of the CHMP AR, with greater variability in feedback
- Some comments:
  - 'Request for supplementary information clear and well written'
  - 'The Request for Supplementary Information did not include any scientific discussion, but an overall recommendation followed by a list of questions and follow up measures following marketing authorisation. One had to go back to the preliminary AR to find the scientific rationale for the additional requested information'.

Centralised Applications Performance Indicators

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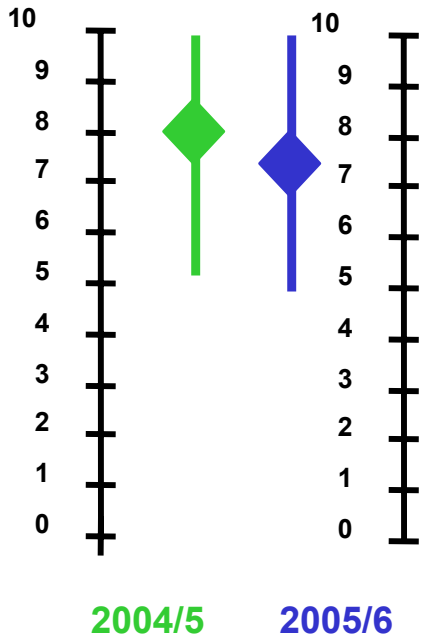
  - Quality of scientific discussion in the Assessment Report
  - **Adequacy of the EPARs**

Clarity of the EPARs (Q75)



Slightly lower level of satisfaction in the clarity of clinical EPARs compared to previous year

- Concerns about timing of publication of updated EPAR

•'We made extensive suggestions for a revised EPAR summary & EPAR most of the recommended changes were implemented but took some time to be posted onto the EMEA website'

•Due to EMEA heavy backlog with EPARs and new requirements that these are published shortly after the CHMP opinion is issued, we were required to review the proposed text in a far too short timeframe. The document was forwarded to us before the Christmas holidays (Dec. 21st) with request to provide comments by Jan. 5th.

- Concern about confidentiality

'..confidential data were published by the EMEA as the submitted comments from the holder were not included. However, the corrected document was published soon afterwards'

Conclusions
Positive points

- Guidance provided by (Co)-Rapporteurs, PTLs, and from EMEA meetings generally good during pre-submission
- Guidance provided by PTLs during the procedure generally very good, although greater variability observed than previous year
- Rapporteur guidance is still at very high level, similar to previous year
- Contactability with PTLs generally very satisfactory
- Communication with Co-Rapporteurs much improved compared to previous year

Conclusions
Areas for improvement

- Level of guidance from (Co)-rapporteurs - significant improvement from previous year although could still be further improved during the procedure
- Slight drop in satisfaction with the quality of the scientific discussion in the CHMP Assessment Report (clinical)
- Slight reduction in clarity of clinical EPARs; and timings & procedures for updating EPARs after a type II variation would benefit from review