



European Federation of Pharmaceutical
Industries and Associations

EFPIA Performance Indicators Extension of Indications 2007-2008

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EMA-EFPIA Info Day 24 February 2009

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 - Changes compared to 2005/2006
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Particulars of the survey

- Survey type II variations for new indications
- Procedures finalised between October 1 2006 and October 30 2008
- Excludes duplicates, includes withdrawals
- Total relevant procedures: 80
- Total questionnaires returned: 53 (66%)
- Positive opinion: 48
- Withdrawals: 5



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Summary of key responses

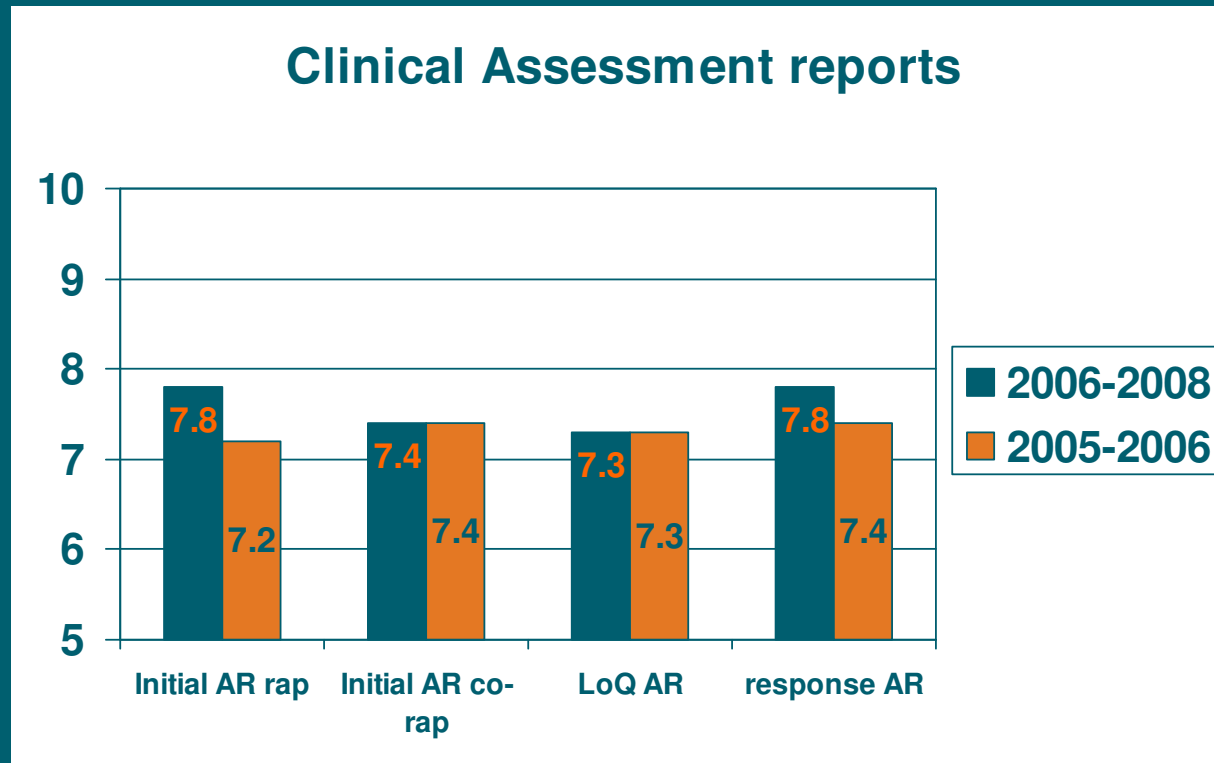
Differences new applications

- Responses reflect that procedures are generally less complex than new applications
 - Less scientific advice (38% vs. 81%)
 - More positive opinions (91% vs. 78%)
 - Lower incidence clarification meetings (LOQ: 30% vs. 72%; LoUI: 13% vs. 52%) and oral explanations (11% vs. 44%)
 - Generally higher satisfaction marks for various procedural aspects (Q45 – 55, 59-63)

Validation issues (Q15,16)

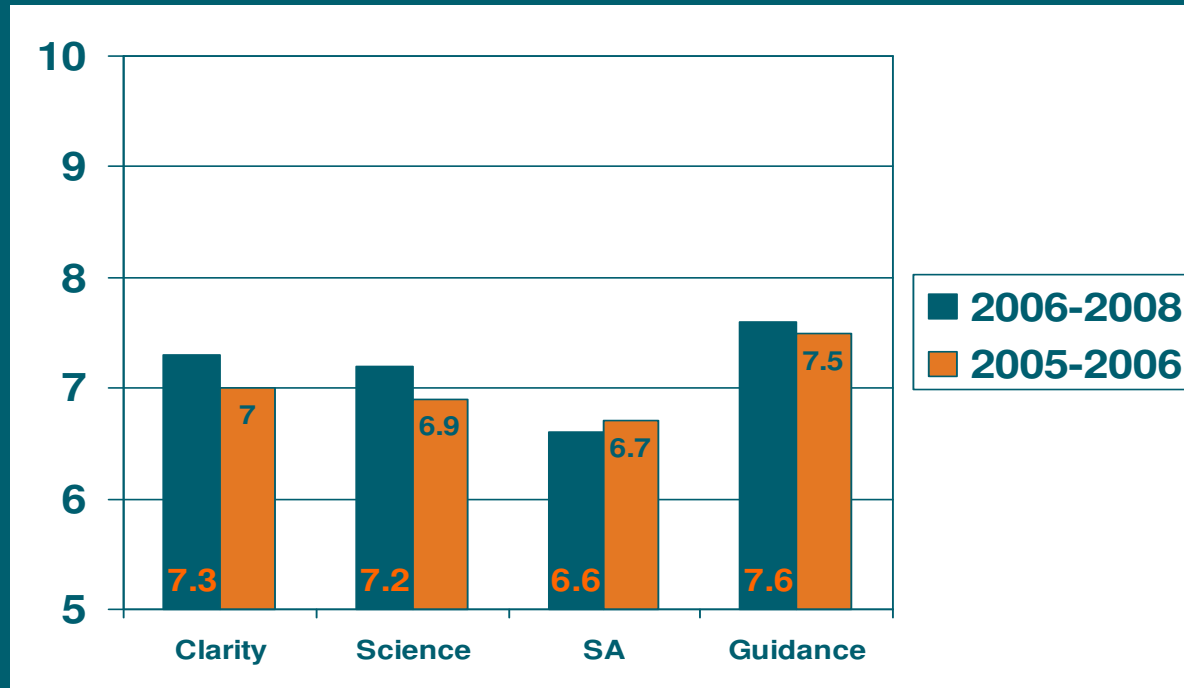
- Large number of spontaneous reports of 'absence of validation issues'. This is in line with observations for new applications
- EMEA guidance well appreciated (average 7.8; range 5-10)
 - Pragmatic/lenient attitude
 - Good communication
 - Pre-submission discussions helpful

Assessment report quality (Q17, 18, 19, 30)



- Work split up between rap. and co-rap.
- Consultation external experts during review may be beneficial
- Errors in AR
- TC for clarification beneficial

List of Questions Day 120 (Q20-23)



Suggestions in free text

- Questions not always clear
- Questions not consolidated/repetition
- Possibility for clarification should be standard

Product Information (Q26-28)

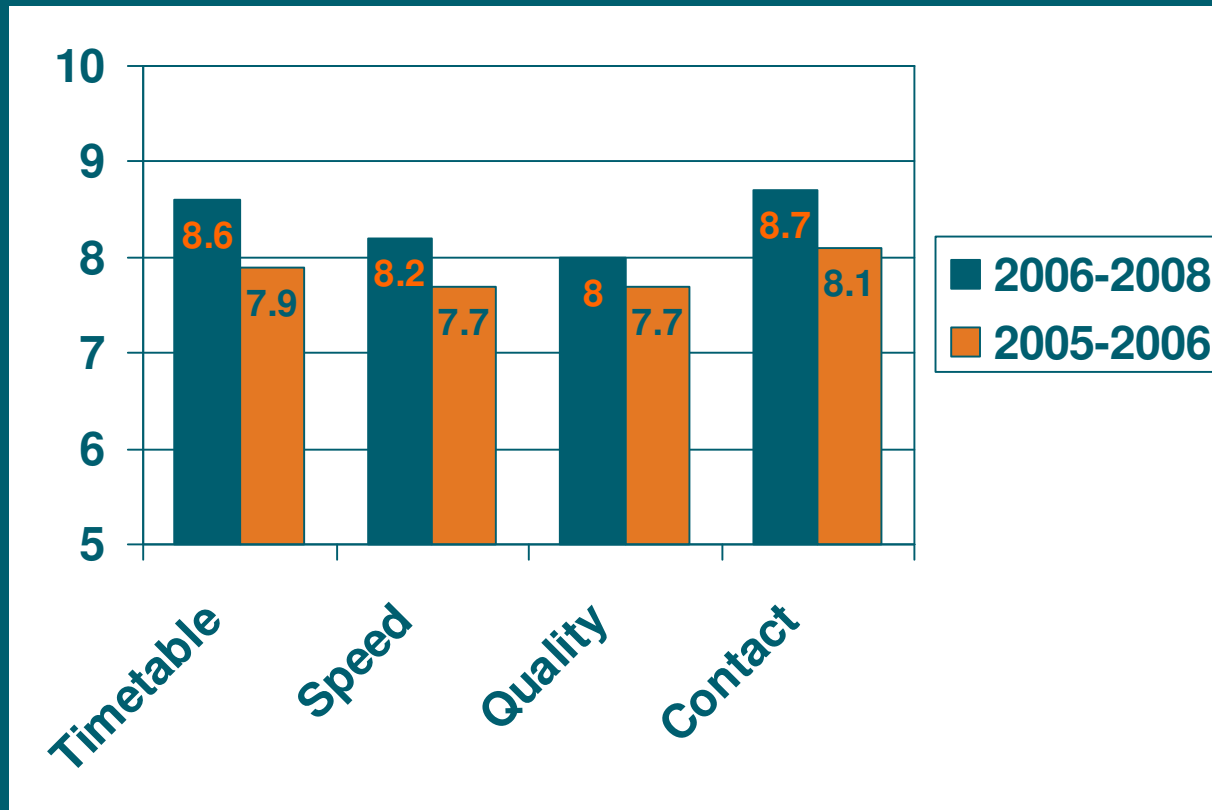
	2006-2008	2005-2006
Assessment user testing	6.8	NA
CHMP proposals PI	7.1	7.2
Clarity PIQ comments	6.3	NA
Clarity QRD comments	7.0	6.8

- Room for improvement
- Main criticisms:
 - Comments not substantiated
 - Comments not consistent

Scientific Advisory Group (SAG) or ad hoc expert panel (Q39-43)

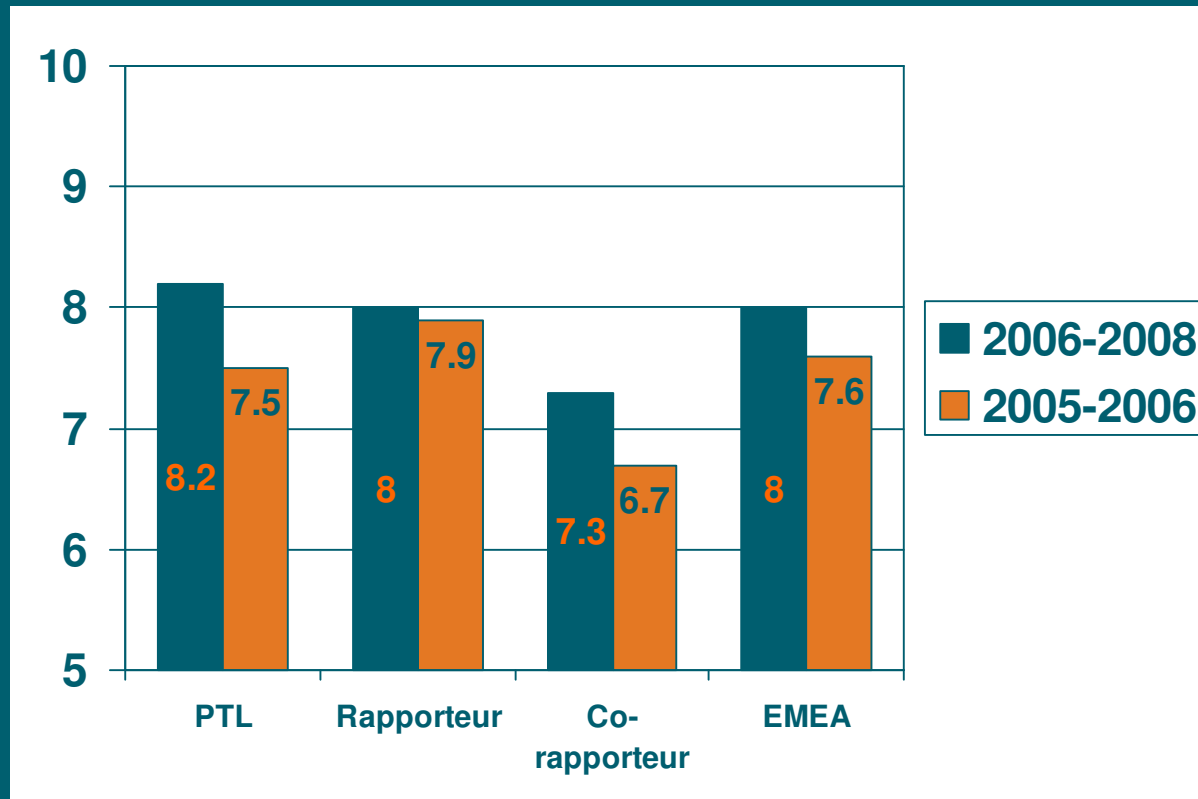
- Infrequent involvement of SAG (9.4%) or expert panel (7.5%) but increasing compared to 2005/6 (0 and 3% resp.)
- Tendency low satisfaction scores:
 - Possibility to participate: 5.4 (range 1-8)
 - Opportunity to prepare for meeting: 5.7 (range 1-8)
 - Quality scientific discussion: 6.2 (range 4-8)
- Main criticisms (small n)
 - Inexperienced SAG/ no continuity
 - Lack of communication/MAH involvement
- Positive effect for rare diseases

Procedure overview (Q45-48)



- Clearly more positive than in 2005-2006
- Lowest scores generally combined low grades for timetable and contact PTL
- Possibly: manage applicant expectations by more clear communication on time-tables

Interaction (Q49-52)



- Generally improved, sometimes not so good, still room for improvement

Success factors:

- Pragmatic approach/ease of contact
- Clarification TCs involving rapporteur and co-rapporteur helpful
- Smooth transition in case of changes in review team

Linguistic Process (Q53-55)

	2006-2008	2005-2006
Member States comments to applicant	7.6	6.8
EMEA support for feedback Member States	7.7	8.0
Linguistic process by NCA	7.4	7.2

- Feedback on issues includes:
 - No reaction at all from one or more Member States
 - Late feedback (around or after day 22) from several Member States
 - Wrong translation (n=1)

Decision making process (Q57-60)

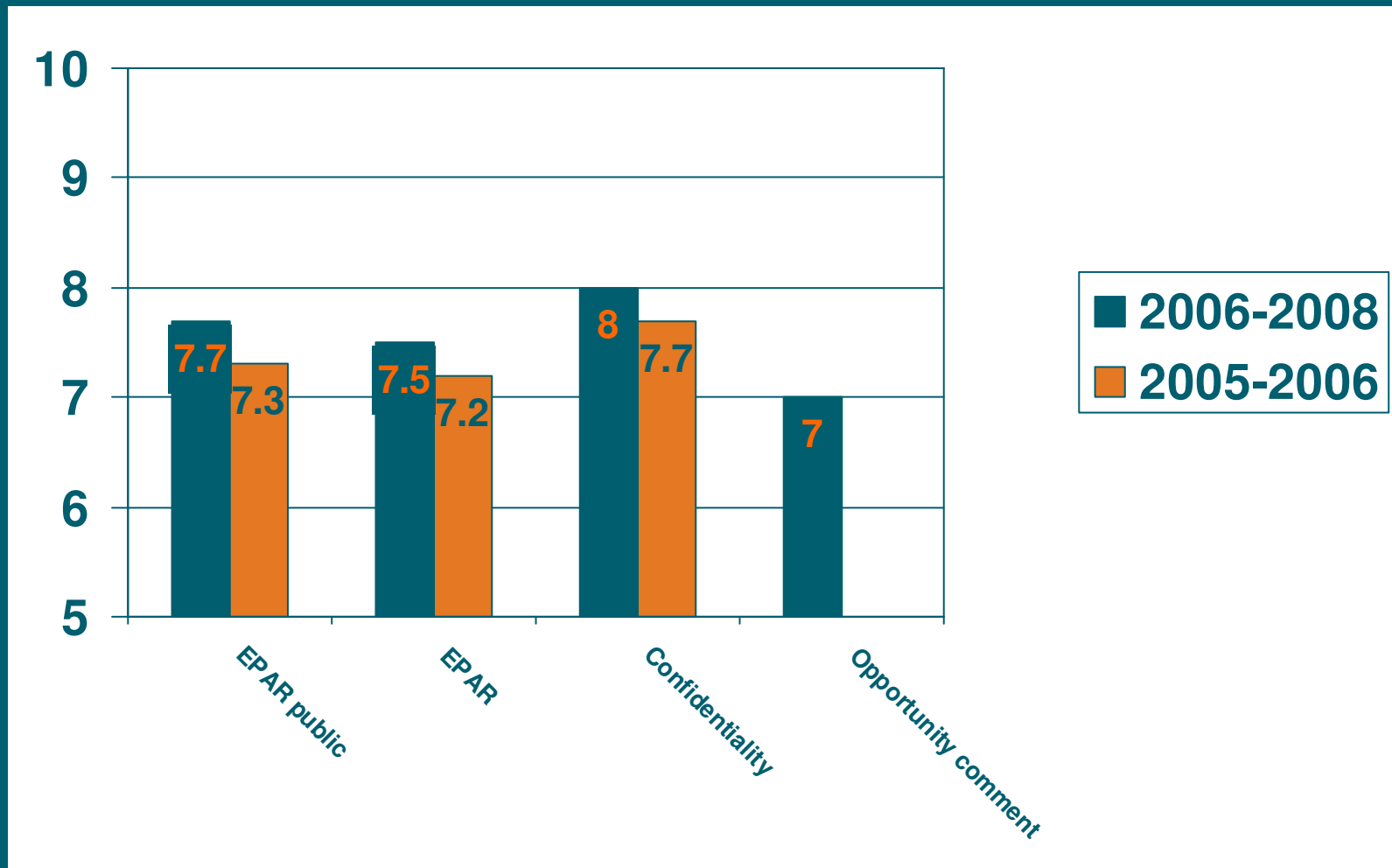
	2006-2008		2005-2006	
Opinion to EC (days)	17	0-53	25.1	3-49
Time to EC decision (days)	29	5-120	24	5-48
Satisfaction duration	8.2		8.1	
EC management	8		8.2	

Final opinion to EC > 27 days: $11/37 = 30\%$

Time to EC decision > 15 days: $30/44 = 68\%$

Time to EC decision > 40 days: $14/44 = 32\%$

EPAR (Q61-63)



Conclusions

- Satisfaction scores higher than for new applications
- Satisfaction scores generally higher than in previous survey
- Good communication and flexible attitude are well appreciated
 - Consistent low scores SAG involvement communication issue
 - Consultation external experts during review beneficial
 - Possibility for clarification should be standard (AR, LoQ, LoOI)
- Perception of 'discordance' between CHMP assessment and scientific advice
- Product information
 - Increase efforts to improve consistency comments
 - Improve substantiation of comments