

EMEA Performance Indicators Extensions of Indications

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Methods

- **Study periods:**

EFPIA Info Day 2009: 01/01/2007 – 31/12/2008

EFPIA Info Day 2007: 01/06/2005 – 31/09/2006

- **Includes:**

All extension of indication procedures with outcome in study period (positive, negative, withdrawal)

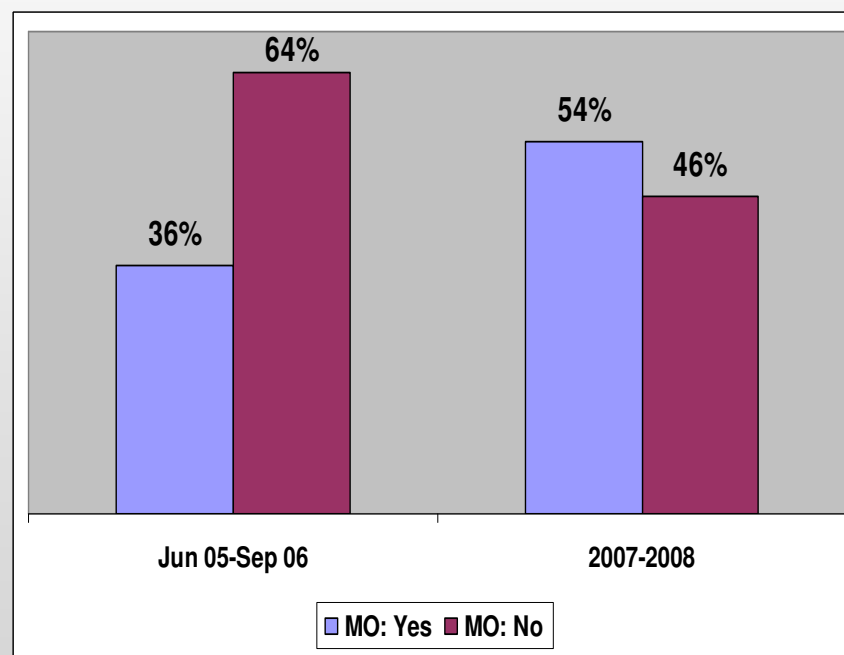
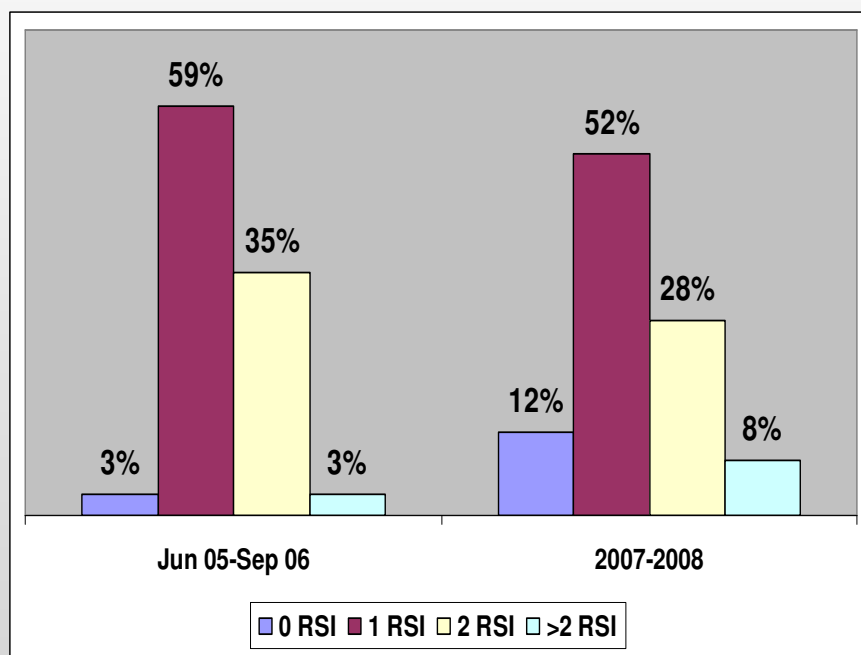
- **Excludes:**

Double-applications

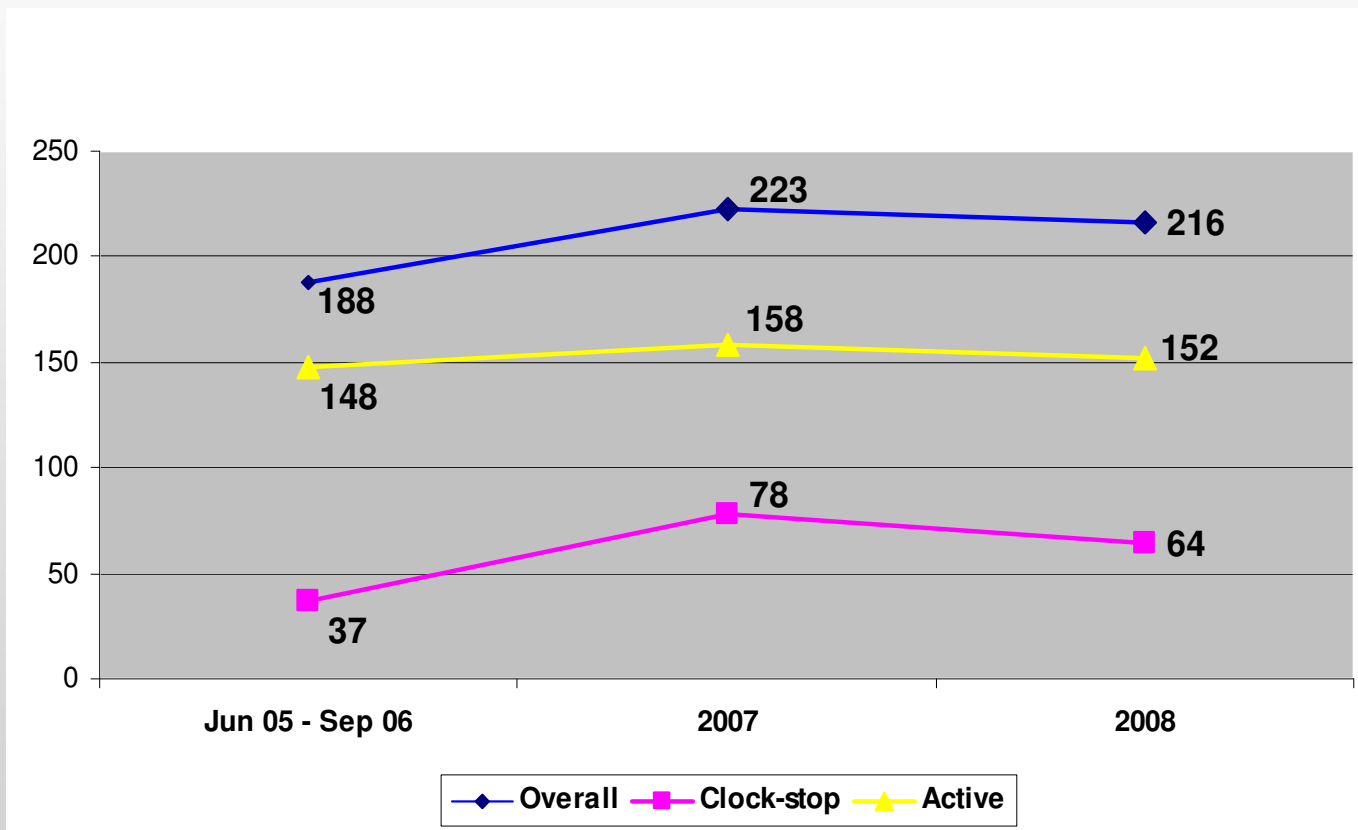
Overview

	Jun.05-Sep.06 (16 months)	2007-2008 (24 months)
Sample	39	85
EMEA SA	8 (21%)	13 (15%)
MO	14 (36%)	46 (54%)
OE	3 (8%)	10 (12%)
SAGs/ <i>ad-hoc</i> expert groups	1 (3%)	8 (9%)

Requests for Supplementary Information and Major Objections

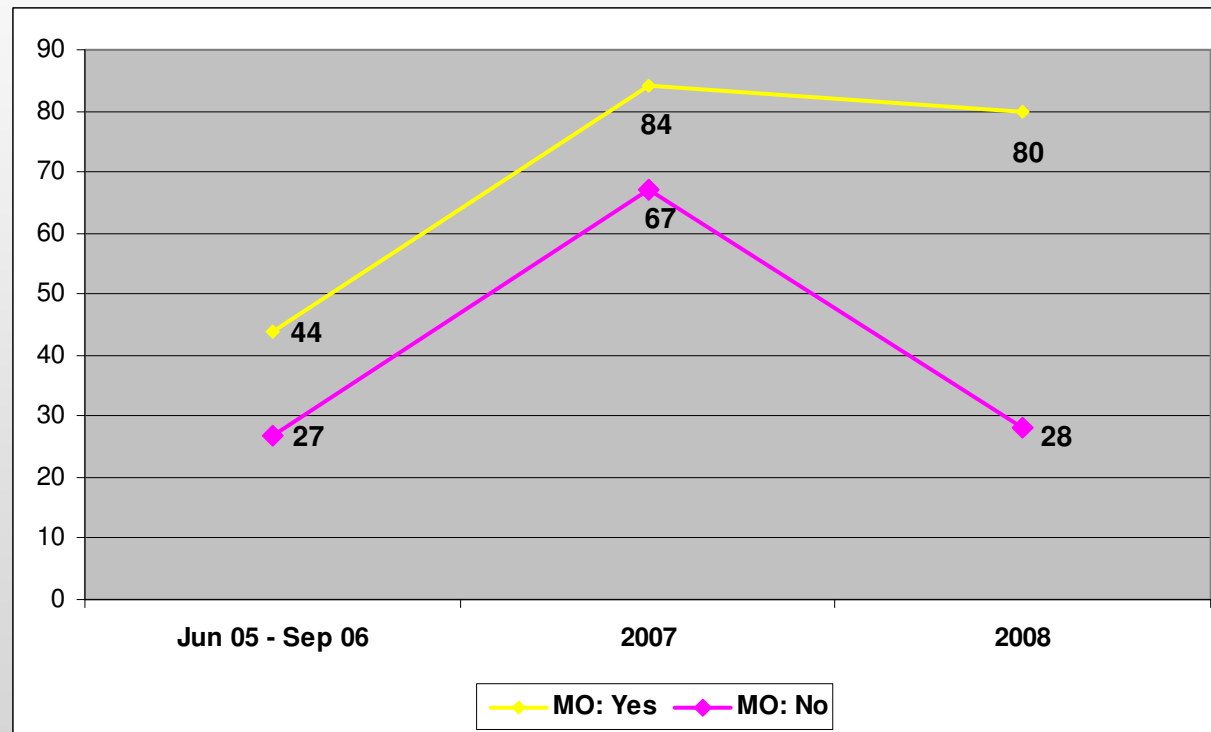


Median Review Times





Median clock-stop times with & without MO



Scientific Advisory Groups & *ad-hoc* expert groups

	SAG Cardiovascular	SAG Anti-inf.	SAG Diabetes/End.	SAG Oncology	Ad-hoc expert group	Total
Jun.05-Sep.06	0	0	0	0	1	1
2007-2008	3*	2	1	1	1	8
Total	3	2	1	1	2	9

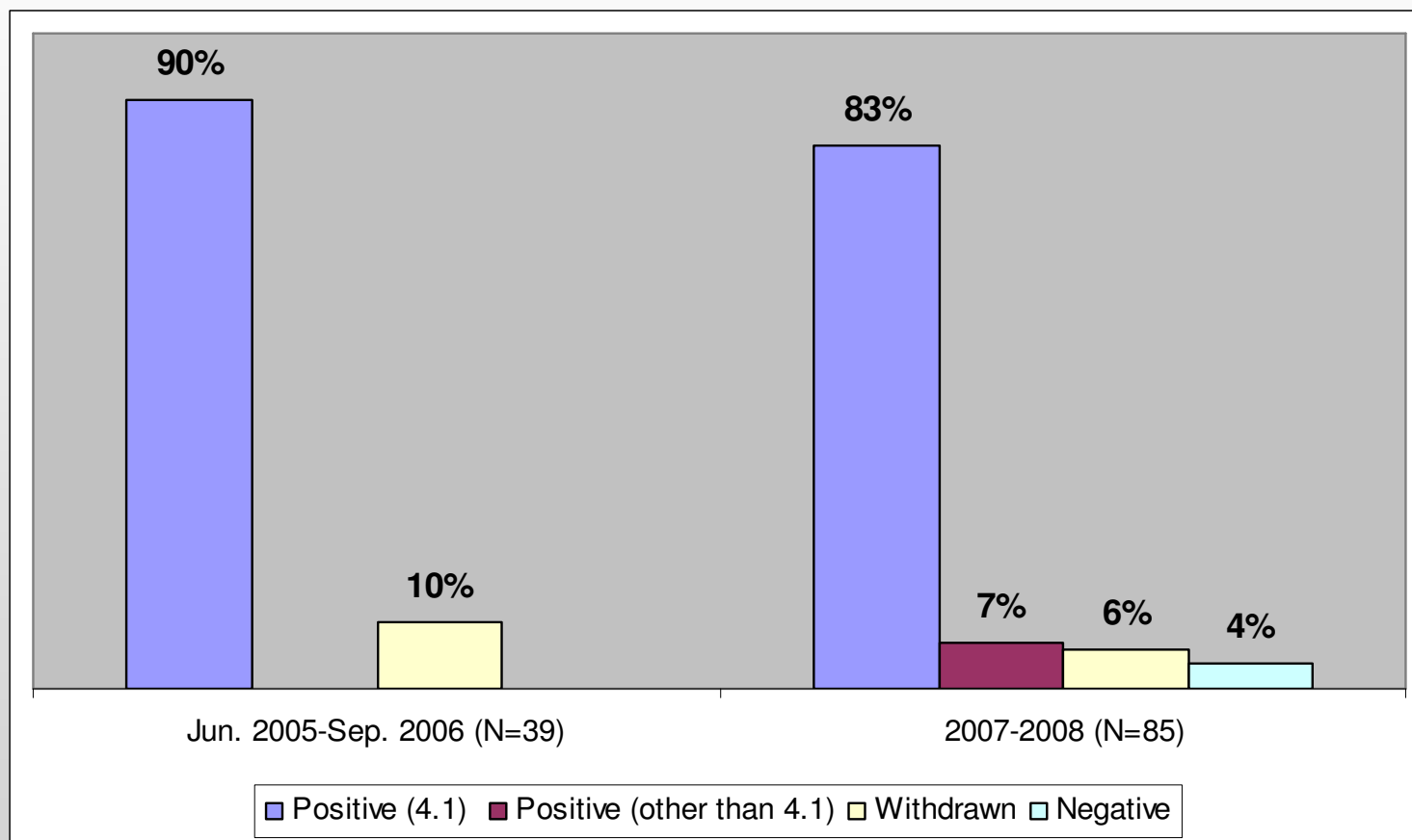
* 3 SAGs for 2 procedures

SAGs / *ad-hoc* expert groups typically convened to assess the ***clinical relevance*** of data to the population applied for, or adequate sub-populations in the context of a concern relating to safety, methodology or effect size/consistency.

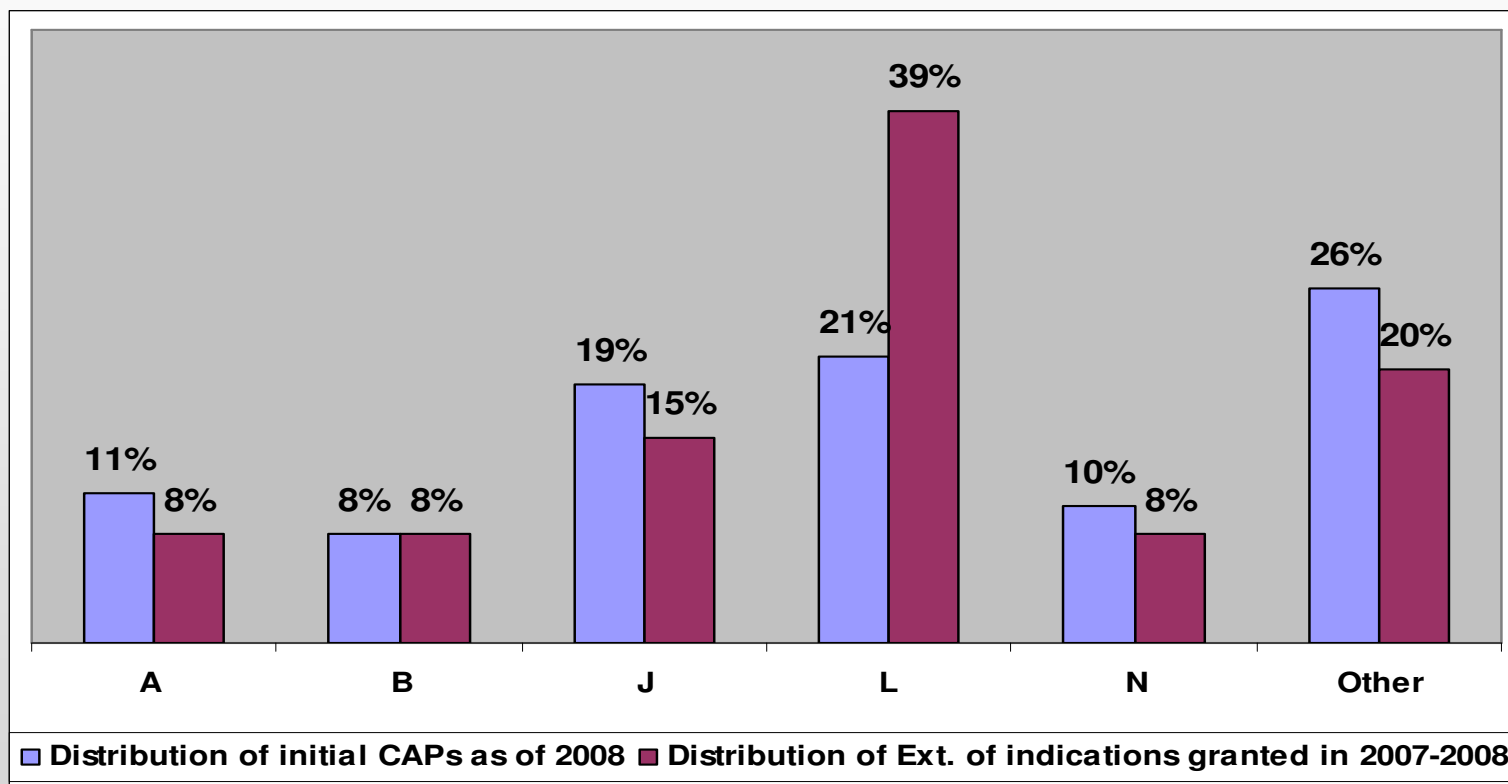
Scientific Advisory Groups & *ad-hoc* expert groups

- Of the 8 procedures with SAG / *ad-hoc* expert group:
 - 4 resulted in a new indication
 - 4 resulted in a negative opinion or a withdrawal
- Procedure outcome always consistent (except in one instance) with SAG recommendations in this sample

Procedure Outcomes



ATC Distribution: new indications vs. initial CAPs



A = Alimentary tract and metabolism; B = Blood and blood forming organs; J = Anti-infective for systemic use; L = Antineoplastic and immuno-modulating agents; N = Nervous system

Questionnaires

Question 1:

Was the dossier presented in a satisfactory way (layout, organisation of data, etc)?

Question 2:

Were all important data/analysis included in the dossier thereby making benefit risk assessment easy?

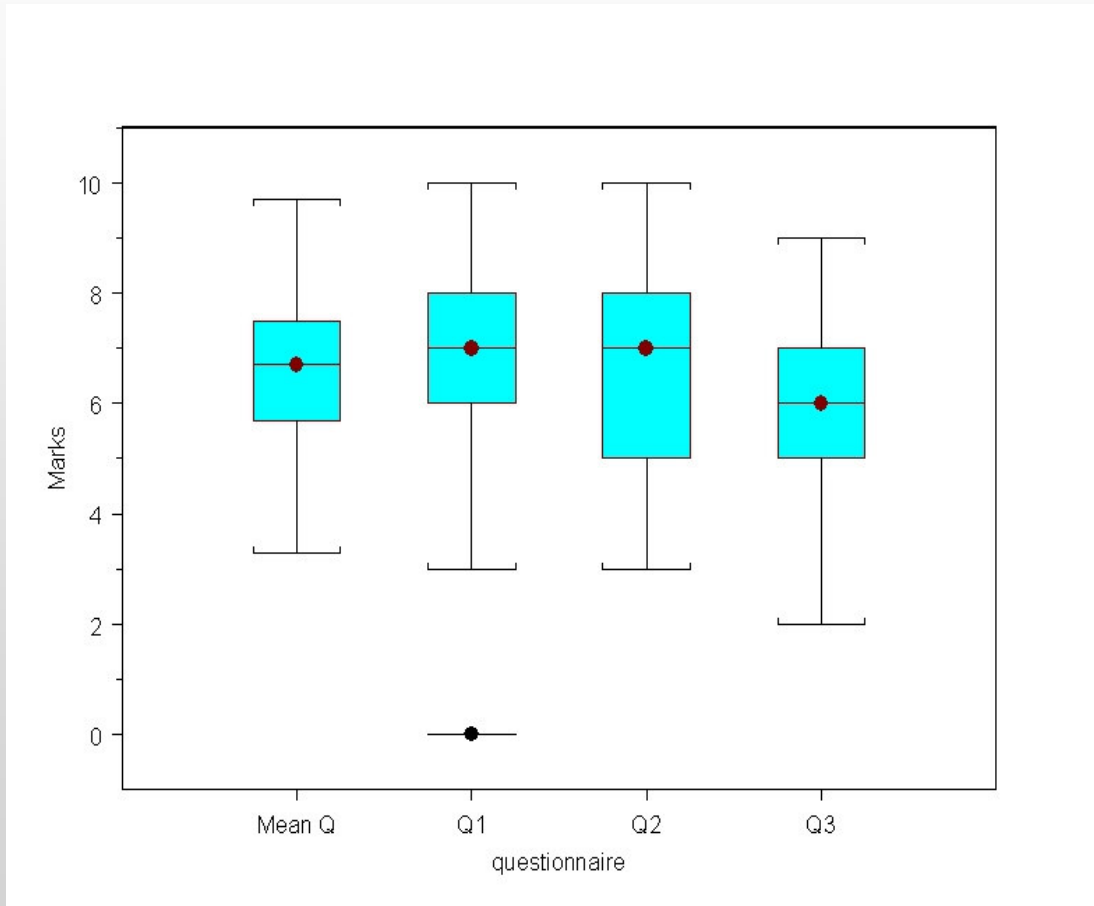
Question 3:

Was the “scientific overview” (expert report) sufficiently critical?

Percentage of procedures with (Co-)Rapporteurs' response:

62% (72% in 2005-06)

Questionnaires: outcome (means)



- Q1=6.9
- Q2=6.6
- Q3=6.1
- Global=6.6

Slightly better scores
than in 2005-06

Questionnaires

- No clear relation between Question 2 score (≤ 5 or > 5) and Major Objections (Yes/No)
(Calculated χ^2 value = 0.03 < tabled χ^2 value (3.84), $\alpha = 0.05$)
- No clear relation between Question 2 score (≤ 5 or > 5) and outcome (new indication or not)
(Calculated χ^2 value = 1.20 < tabled χ^2 value (3.84), $\alpha = 0.05$)

- Higher volume of procedures in 2007-08 compared to 2005-06.
- Longer review times in 2007-08 compared to 2005-06, with longest times in 2007.
- Stabilisation of review times in 2008, in particular due to decreasing clock-stops for procedures without MO.
- More procedures led to MO and required extra CHMP expertise (SAGs) than in 2005-06. Procedure outcomes consistent with SAG recommendations.
- High rate of success (i.e. granting of a new indication), although slightly inferior to that of 2005-06.
- Good level of Rapporteurs' satisfaction with dossier presentation/content. However, no clear relation with procedure outcome/complexity.