efpia

European Federation of Pharmaceutical Industries and Associations

Presentation and Analysis of the EFPIA Questionnaire 06/08 on the Centralised Procedure New Applications

Professor David Jefferys
Senior Vice President
Head of Global Regulatory
Eisai Europe Ltd

24th February 2009

Responses

Period of the questionnaire 1/10/06 to 30/10/08

Approvals

- 64 responses (NAS applications, including orphan applications)
- 111 applications determined over the period (58% of applications captured in the survey)
- 9 orphans (14%)
- 50 positive opinions(78%) (including positive on appeal, conditionals, authorisation under exceptional circumstances)
- 14 negative opinions (22%) (refusal and withdrawals)

Scientific Advice (questions 1 to 8)

- 52 sought advice (including 19 national, 20 combined EMEA and national, 13 EMEA advice only)
- 12 (19%) did not seek advice
- 93% followed the scientific advice (53% responded to this question)
- 4 (8%) discussed conditional approval
- 2 (4%) discussed approval under exceptional circumstances
- 7 (21% - 33 responses) said EMEA scientific advice necessitated major changes in the development plan
- 1 application sought parallel advice and this was granted

Accelerated Assessment (questions 9 – 12)

- 16 requested accelerated assessment 25% [05/06 = 33%]
- 6 granted accelerated assessment [05/06 = 5%]
- 2 approved under accelerated assessment (3%) [05/06 = 5%] (4 converted to normal timetable)
- US/FDA “priority review” granted to 16 of the cohort

Comments: (free text)

- No justification for refusal
- Company “discouraged” to apply x 3

Conditional Approval/Exceptional Circumstances (questions 13-14)

- 6/64 approved “on condition”
- Only 2 applied for conditional approval
- 3/64 approved “under exceptional circumstances” – only 2 applied

Validation Q 16

- No major issues encountered during validation for most applications
- Helpful EMEA guidance during validation

06/08	scale 1-10	05/06
7.1		7.8

Initial Assessment Report (Q17/18)

Rapporteur Q17

Co-rapporteur Q18

Initial Assessment Reports Q17

Satisfaction with the quality, clarity and completeness of the Rapporteurs initial AR (scale 1-10's)	06/08	05/06	04/05
Quality	7.4	7.8	7.7
Non-clinical	7.5	7.9	7.8
Clinical	7.0	7.8	7.7
RMP	7.0	new	-

Initial Assessment Reports Q18

Co-rapporteurs AR	06/08	05/06	04/05
Quality	7.1	7.3	7.5
Non-clinical	7.4	7.4	7.6
Clinical	6.7	6.9	7.4
RMP	7.1	new	-

CHMP List of questions (Q19-21) (Scales 1-10)

Q19. Satisfaction with quality, clarity and completeness of the CHMP AR	06/08	05/06	04/05
Quality	7.4	7.7	7.6
Non-clinical	7.6	7.8	7.8
Clinical	7.0	7.5	7.6
RMP	7.3	NEW	-

CHMP List of questions (Q19-21) (Scales 1-10)

Q20. Lo Q	06/08	05/06	04/05
Clear and understandable			
Quality	7.5	7.5	7.7
Non-clinical	7.8	7.8	7.9
Clinical	7.3	7.4	7.3
Q21 Questions adequately substantiated			
Quality	7.3	7.5	7.3
Non-quality	7.4	7.7	7.7
Clinical	7.2	7.3	7.2

Compliance in the assessment with CHMP Scientific Advice and CHMP Guidance Documents

Q22. Compliance with Scientific Advice	06/08	05/06	04/05
Quality	6.8	7.1	9.3
Non-clinical	7.7	7.7	9.3
Clinical	6.9	6.7	* 7.0 (very small sample)

Compliance in the assessment with CHMP Scientific Advice and CHMP Guidance Documents

Q23. Compliance with CHMP Guidance Documents	06/08	05/06	04/05
Quality	8.0	7.8	8.9
Non-clinical	8.0	7.3	8.8
Clinical	7.7	7.3	8.8

Product Literature Q25 - 29

(Scales 1-10)

	06/08	05/06	04/05
Q25 CHMP Proposals on Product Information	6.7	7.4	7.7
Q26 Satisfaction with user testing report	6.9	New	New
Q27 P1Q comments	6.5	New	New
Q28 QRD comments on Product Information	6.5	7.0	New
Q29 Usefulness of QRD meeting	7.7	7.9	-

efpia

Response Assessment Report

Q30. Satisfaction with the clarity, quality and completeness of the Response AR	06/08	05/06	04/05
Quality	7.6	8.0	8.1
Non-clinical	7.8	8.0	7.9
Clinical	7.0	7.7	7.8

Oral Explanation (Q33-38)

	06/08	05/06	04/05
Oral explanation scheduled	44% (28)	39%	10%
Sufficient opportunity for preparation	6.0	7.5	6.5
Was a requested clock stop granted?	19%	New	New

Oral Explanation (Q 33-38)

	06/08	05/06	04/05
Were CHMP discussions during the OE interactive?	4.2	5.2	7.5
Scientific adequacy of the CHMP discussions during the OE	4.9	5.7	7.5
Feedback on the CHMP review	6.8	7.2	8.5

Scientific Advisory Groups, Expert Panels Q39 -43

	06/08	05/06	04/05
Q39 Involvement of a SAG in dossier assessment	13%	16%	-
Q40 Involvement of ad hoc panel/WG	6%	14%	-
Q41 appropriate possibility to participate in discussions (scale 1-10)	5.8	5.8	-
Q42 Sufficient opportunity for preparation	6.0	7.1	-
Q43 Quality of scientific discussion	5.0	6.7	-

Procedure Overview (Q45 – 48)

	06/08	05/06	04/05
Was the timetable appropriately set?	7.7	8.0	New
Satisfaction with the speed of the CP	7.4	7.8	7.8
Satisfaction with the quality of the scientific assessment	7.0	7.8	8.1
EMEA product team leader was approachable	8.1	8.0	8.7

Interaction with the EMEA/Rapporteurs (Q49 - 56)

	06/08	05/06	04/05
Satisfaction with the communication, transparency, guidance, management of the process by EMEA team leader	7.7	7.6	8.4
Satisfaction with Rapporteur (process)	7.2	8.1	7.3
Satisfaction with Co-rapporteur process	6.8	6.9	7.6

Interaction with the EMEA/Rapporteurs contd….

	06/08	05/06	04/05
Satisfaction with the EMEA management of the process to the decision	7.7	7.9	8.3

Interaction with the EMEA/Rapporteurs contd….

	06/08	05/06	04/05
Post Opinion (Q55)			
Satisfaction with linguistic process by national competent authorities	6.1	6.4	-

The EC Decision Making Process (Q59, 60)

	06/08	05/06	04/05
Duration of the decision making process was satisfactory	7.1	7.9	6.9
Satisfaction with the EC management of the final decision process	7.0	7.8	New

European Public Assessment Report (EPAR)

	06/08	05/06	04/05
EPAR was clear and understandable			
Quality content	7.3	7.4	7.4
Non clinical	7.0	7.3	7.9
Clinical	6.8	7.1	7.3
Protection of commercially confidential data			
Quality	7.3	7.7	6.9
Non-clinical	7.6	7.9	7.0
Clinical	7.4	7.6	7.1

European Public Assessment Report (EPAR)

	06/08	05/06	04/05
Time to publication of the EPAR after the Commission's decision	33.3	34	
Sufficient opportunity to comment on the EPAR (scale 1-10)	6.9	66% (said yes)	

Conclusions (1)

- 64 responses (58% of the completed procedures doing the survey period)
- Increasing proportion of requests for EMEA/CHMP scientific advice
- Higher percentage (22%) of procedures ended in Rejection or Withdrawal (in 06/08) than in previous periods
- Many free text reports of inconsistencies in the assessment of product information by CHMP, QRD/PIQ

Conclusions (2)

- More satisfaction with the rapporteur than the co-rapporteur, but the rapporteur score has fallen between 05/06 and 06/08
- NML increased the speed of decision making. The speed has been maintained over the last 2 years, but satisfaction with this part of the procedure has dropped. Does industry have higher expectations?
- Scientific quality and interactiveness of the OE and of the SAG/expert groups are rated even lower than the last survey

efpia

Conclusions (3)

- Most satisfaction scores are lower than the 2005/06 survey, particularly concerning clinical aspects of the assessment [scores from procedures with negative outcomes are mostly lower than those from positive outcomes]
- Perception of overall scientific quality of assessment has decreased again
- New programme of 2004 NML for conditional approval, accelerated assessment and approval under exceptional circumstances are used infrequently. Most products do not get to patients more rapidly as a result of these provisions