



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2009 report on the interaction with Patients' and Consumers' Organisations

PCWP plenary meeting

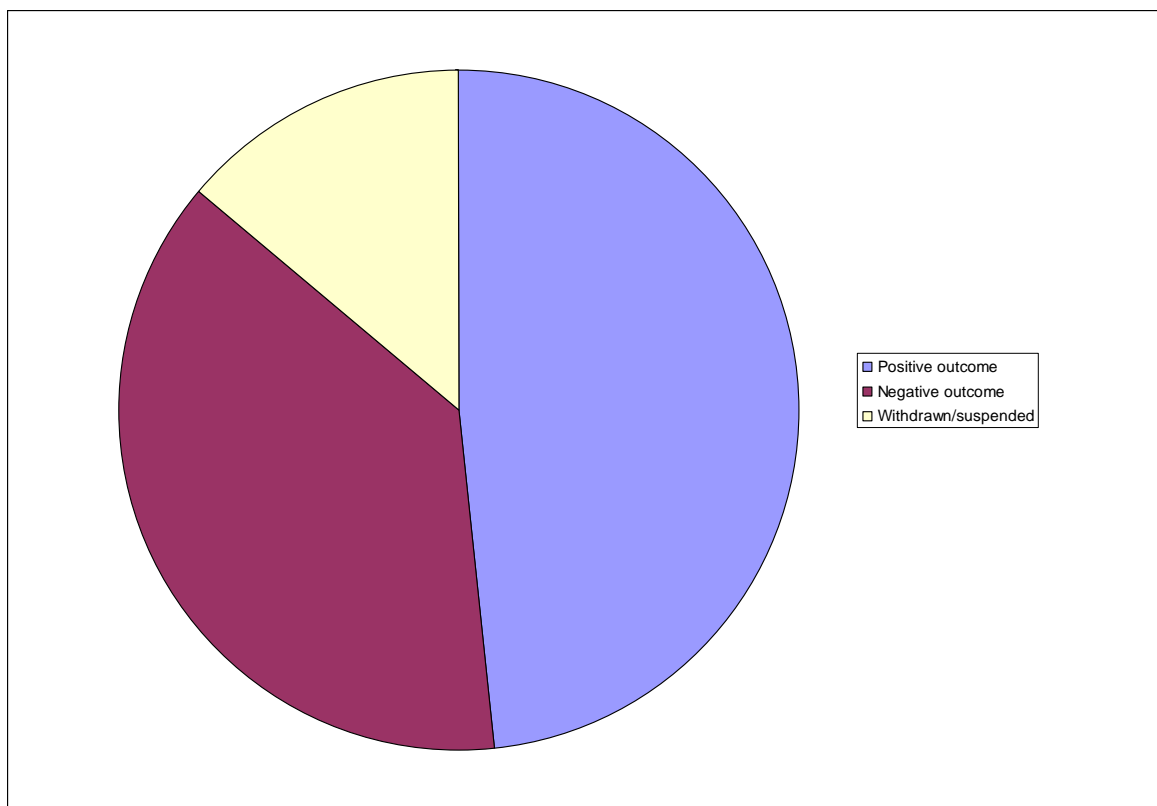
16 June 2010





Overview of PCOs evaluation

So far, 58 PCOs have applied for eligibility:
28 positive, 22 negative, 8 suspended/withdrawn





Patients' and Consumers' Organisations working with EMA in 2007-2009

	Name of the organisation	Fulfilment of EMA eligibility criteria	Involvement in 2009	Involvement in 2008	Involvement in 2007
1	Alzheimer Europe (AE)	YES	YES	YES	YES
2	European AIDS Treatment Group (EATG)	YES	YES	YES	YES
3	European Cancer Patient Coalition (ECPC)	YES	YES	YES	YES
4	European Federation of Allergy and Airways Diseases Patients' Associations (EFA)	YES	YES		
5	European Federation of Neurological Associations (EFNA)	YES	YES	YES	YES
6	European Genetic Alliances' Network (EGAN)	YES	YES	YES	YES
7	European Heart Network (EHN)	YES	YES	YES	
8	European Multiple Sclerosis Platform (EMSP)	YES	YES	YES	
9	European Myeloma Platform (EMP)	YES	YES	YES	YES
10	European Older People's Platform (AGE)	YES	YES		
11	European Organisation for Rare Diseases (EURORDIS)	YES	YES	YES	YES
12	European Parkinson's Disease Association (EPDA)	YES	YES	YES	YES
13	European Patients' Forum (EPF)	YES	YES	YES	YES
14	European Public Health Alliance (EPHA)	YES	YES	YES	YES
15	Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe)	YES	YES		
16	Health Action International (HAI)	YES	YES	YES	YES
17	Insulin Dependent Diabetes Trust (IDDT)	YES	YES	YES	YES
18	International Alliance of Patients' Organizations (IAPO)	YES	YES	YES	YES
19	International Diabetes Federation (IDF)	YES	YES	YES	YES
20	International Patient Organisation for Primary Immunodeficiencies (IPOPI)	YES	YES	YES	YES



	Name of the organisation	Fulfilment of EMA eligibility criteria	Involvement in 2009	Involvement in 2008	Involvement in 2007
21	Myeloma Euronet (ME)	YES	YES	YES	YES
22	Rett Syndrome Europe (RSE)	YES	YES	YES	
23	Thalassaemia International Federation (TIF)	YES	YES	YES	
24	The European Consumers' Organisation (BEUC)	YES	YES	YES	YES
25	The International Confederation of Childhood Cancer Parents Organisations (ICCCPO)	YES	YES	YES	
26	Action Duchenne UK	NO	YES		
27	Charley's Fund, USA	NO	YES		
28	Cure Duchenne, USA	NO	YES		
29	Duchenne Ireland	NO	YES		
30	Duchenne Parent Project	NO	YES		
31	European Network of Fibromyalgia Associations (ENFA)	NO	YES		
32	Forschung und Therapie fuer SMA	NO	YES		
33	Gaucher Gesellschaft Deutschland E.V. (GGD E.V.)	NO	YES		
34	Muscular Dystrophy Association (MDA)	NO	YES	YES	
35	Muscular Dystrophy Campaign, UK	NO	YES		
36	Parent Project Australia	NO	YES		
37	Parent Project Onlus Italy	NO	YES		
38	Thalidomide UK	NO	YES		YES
39	TREAT-NMD Neuromuscular Network	NO	YES	YES	
40	United Parent Projects Muscular Dystrophy (UPPMD)	NO	YES	YES	
41	Vaincre la Mucoviscidose	NO	YES		



Patients and consumers have participated in EMA activities during 2009 as:

- Members of committees/working parties
- Experts
- Representatives of organisations



Activities in which patients and consumers were involved as members of committees/working parties

Members of the Management Board	2
Members and observers of the COMP	3
Members and alternates of the PDCO	3+3
Members and alternates of the CAT	2+2
PCWP	10+8
Observers at the HCP WG	2
Total	35



Main activities in which patients and consumers were involved as experts

Working Group on Clinical Trials in third countries	6
SAG meetings	3
PhVWP consultations	3
SAWP discussions	3
Q&A preparation	2
Workshops	16
Review of EPAR summaries	36
Review of Package Leaflets	33
...	
Total	108

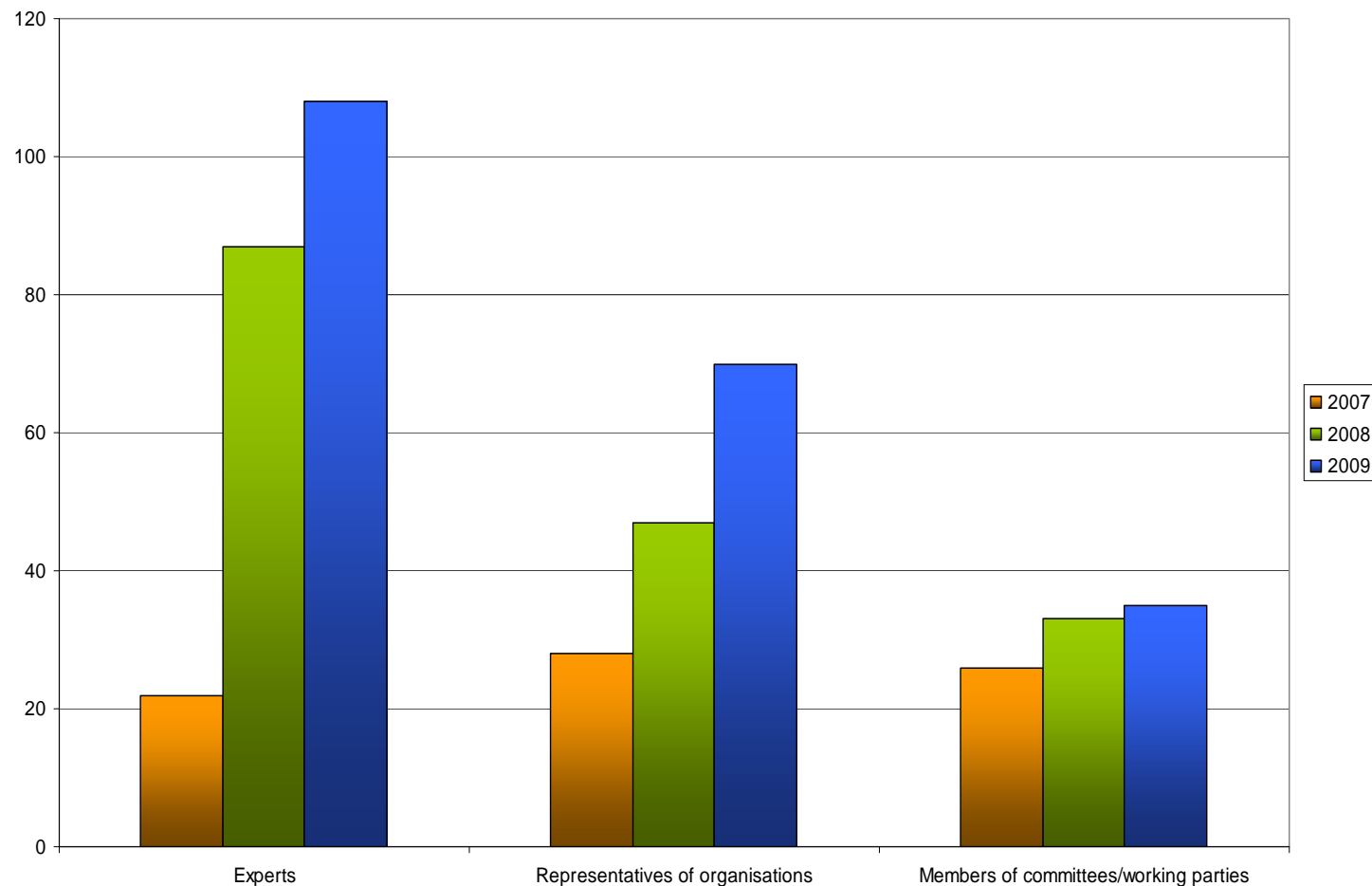


Main activities in which patients and consumers were involved as representatives of organisations

Pilot phase observers at PhVWP	2
Meeting with EC on the pharma-package	9
PhVWP consultations	16
Input on EMA corporate identity	10
Meetings of ENCePP	1
Meetings of PROTECT	1
Workshops on Transparency Policy	9
EudraCT information day	3
CHMP consultations	3
...	
Total	70

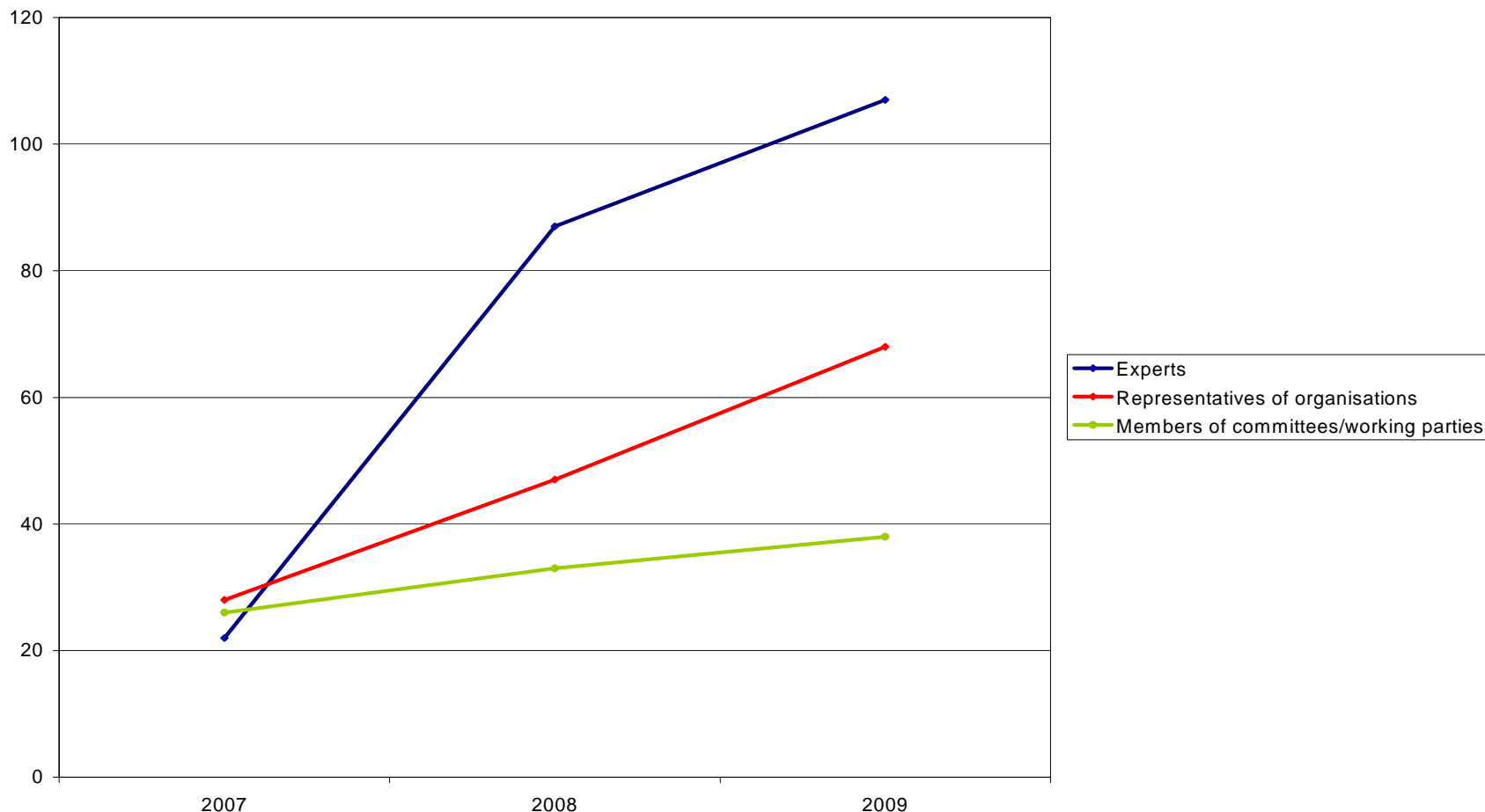


Involvement of patients and consumers in EMA activities in 2007-2009



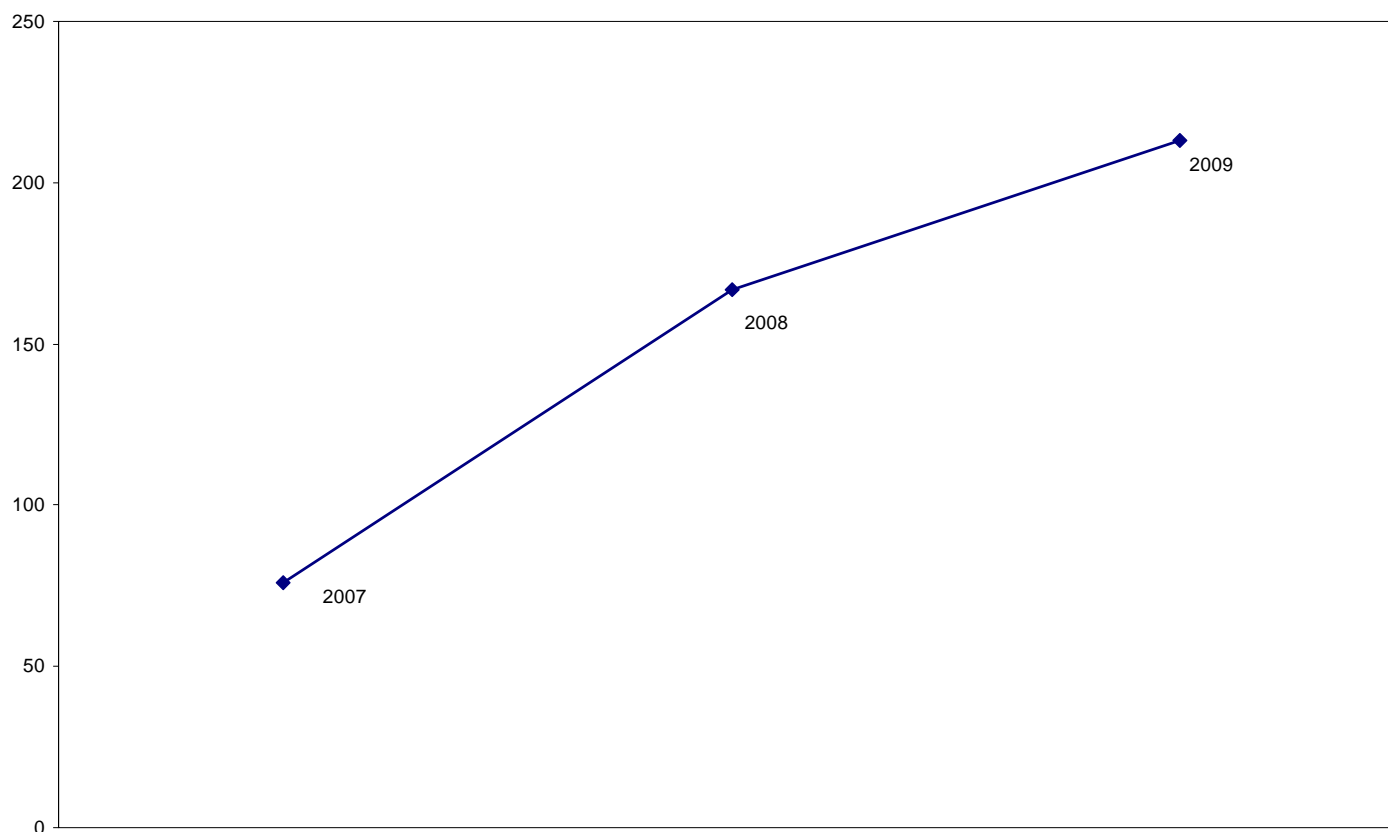


Patients and consumers involved in EMA activities in 2007-2009



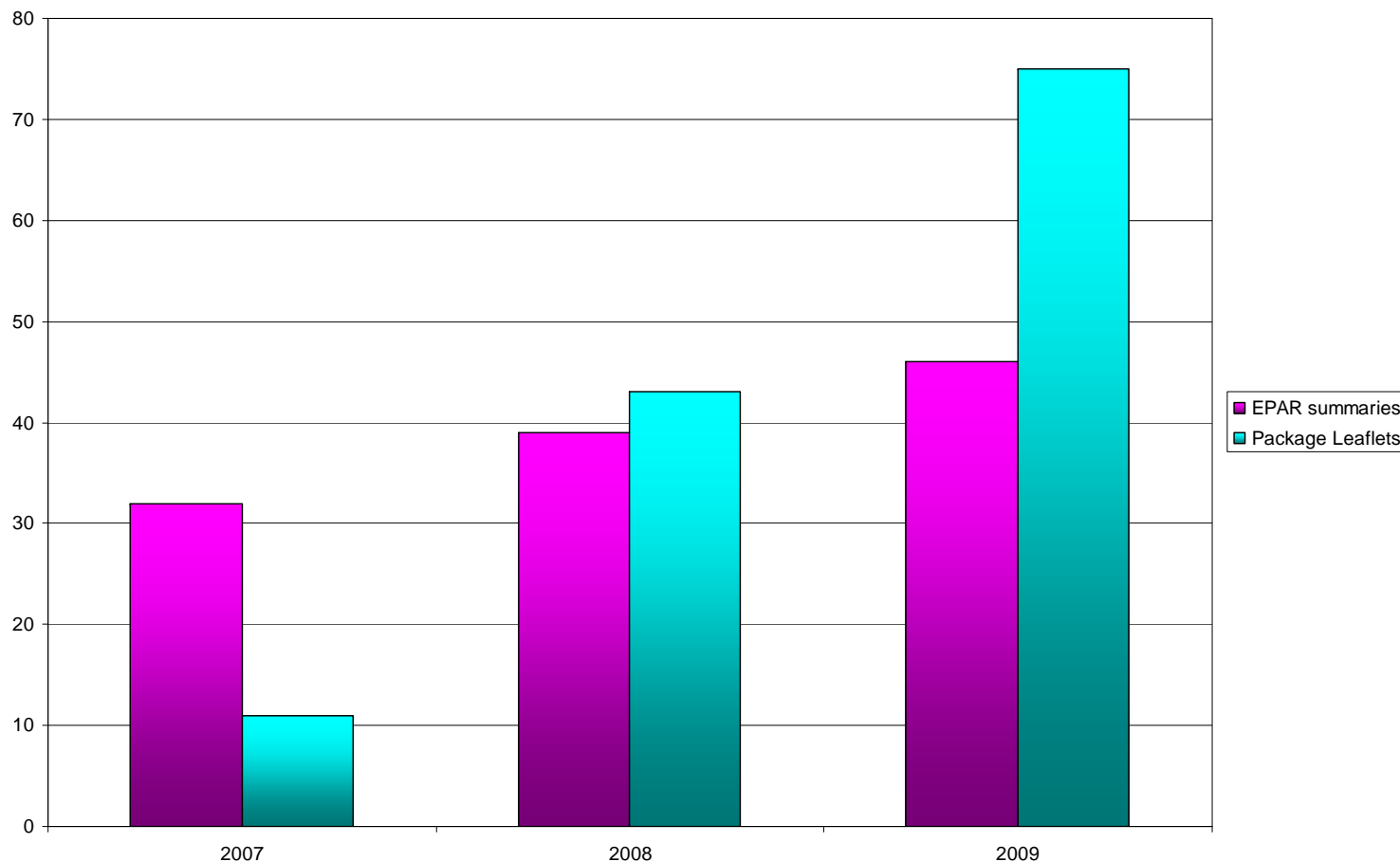


Total number of patients and consumers involved in EMA activities in 2007-2009





Review of EPAR summaries and Package Leaflets





Conclusions

- 2009 has seen a further increase in the level of involvement of patients and consumers in EMA activities
- Clear distinction of patients/consumers involvement as:
 - Members
 - Experts
 - Representatives
 - Observers
- 2009 report to be circulated to PCWP by the end of June 2010 for comments



Next steps

- The “Framework of interaction” between the EMA and PCOs will be extensively revised during 2010:
 - PCOs representatives will continue to be involved in the preparation of information oriented to patients and the general public
- Further involvement:
 - Benefit/risk assessment
 - Training
 - Role in scientific committees
 - Emerging safety issues



Thank you for your attention