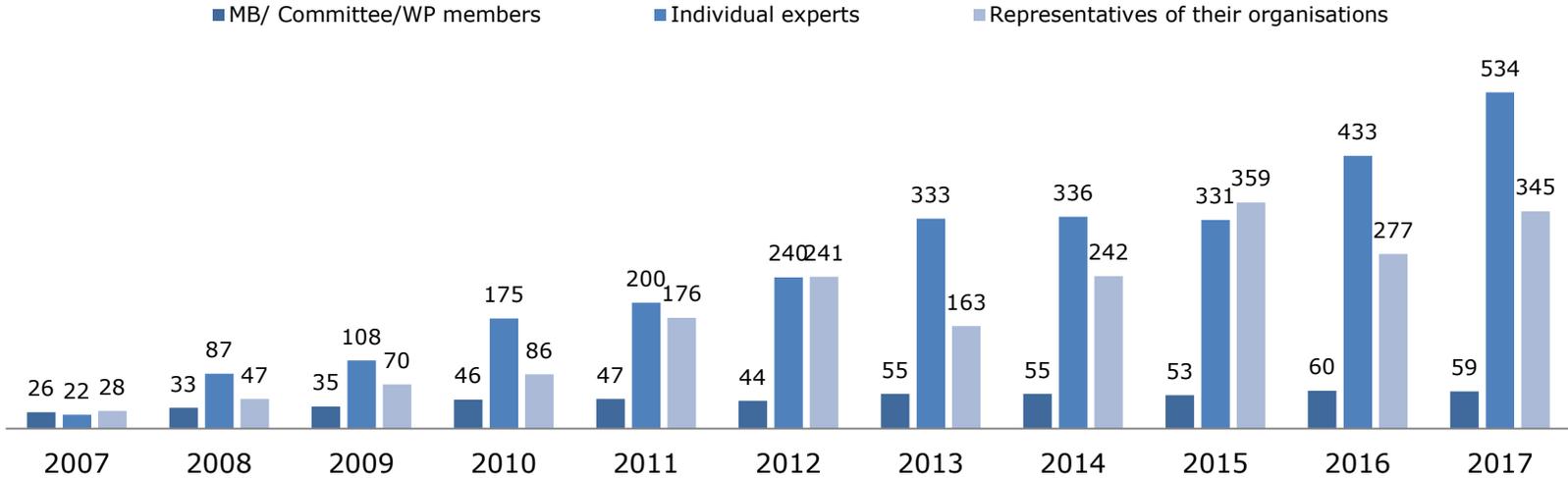


Annexes to the Stakeholder engagement annual report 2017

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Annex I: Involvement in EMA activities (2009-2017)

A: Patients and consumers



B: Healthcare professionals



Annex II: Membership of patients and healthcare professionals in EMA Management Board and Scientific Committees

A: Membership of patients in EMA management board and scientific committees

| EMA Management Board and Scientific Committees | Members /alternates |
|--|---------------------|
| Governance: | |
| Management Board (MB) | 2 |
| Scientific Committees: | |
| Committee for Orphan Medicinal Products (COMP) | 3 |
| Paediatric Committee (PDCO) | 3 / 3 |
| Committee for Advanced Therapies (CAT) | 2 / 2 |
| Pharmacovigilance and Risk Assessment Committee (PRAC) | 1 / 1 |
| TOTAL | 17 |

B: Membership of healthcare professionals in EMA management board and scientific committees

| EMA Management Board and Scientific Committees | Members /alternates |
|--|---------------------|
| Governance: | |
| Management Board (MB) | 2 |
| Scientific Committees: | |
| Paediatric Committee (PDCO) | 3 / 3 |
| Committee for Advanced Therapies (CAT) | 2 / 2 |
| Pharmacovigilance and Risk Assessment Committee (PRAC) | 1 / 1 |
| TOTAL | 14 |

Annex III: Membership of patients and healthcare professionals in EMA working parties

A: Patient and consumer membership of working parties

| Membership of working parties (WP) | Members / alternates (observers) |
|--|----------------------------------|
| Patients and Consumers Working Party (PCWP) + co-chair | 20+1 / 21 |
| HealthCare Professionals Working Party (HCPWP) | 2 |
| TOTAL | 40 |

B: Healthcare professional membership of working parties

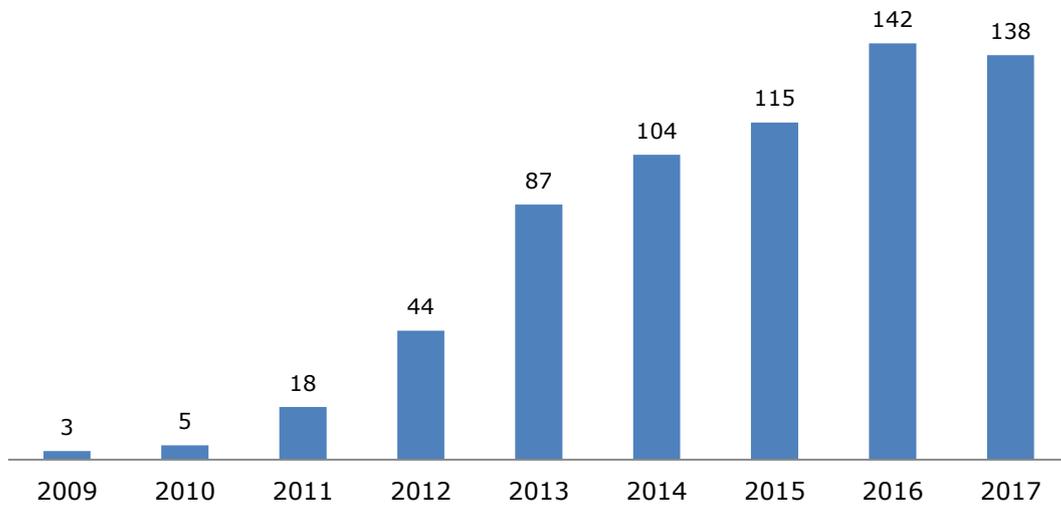
| Membership of working parties (WP) | Members |
|---|-----------|
| HealthCare Professionals Working Party (HCPWP) + co-chair | 19 / 22+1 |
| Patients and Consumers Working Party (PCWP) | 1 |
| TOTAL | 43 |

Annex IV: Workshops attended by patients and healthcare professionals in 2017

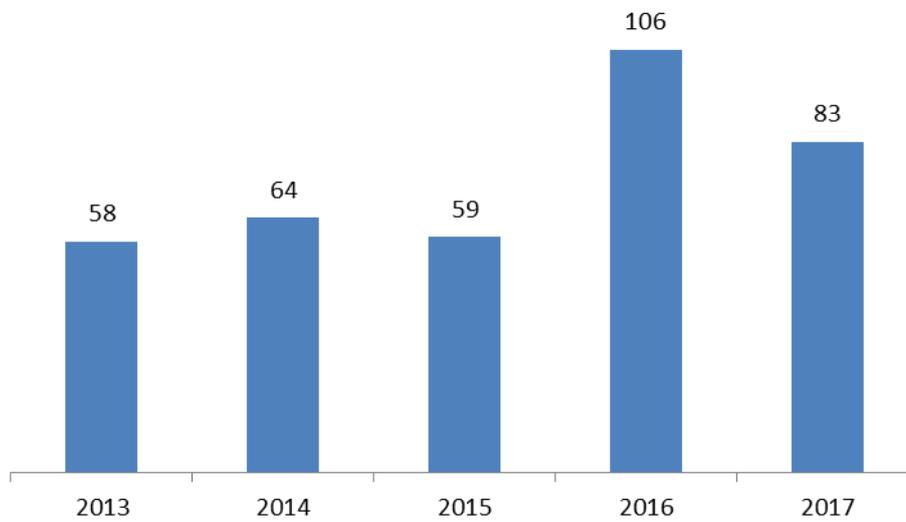
| Month | Workshop | Patients | HCP |
|-----------|---|----------|-----|
| January | Multi-stakeholder paediatric oncology strategy workshop (cancers with anaplastic lymphoma kinase aberrations) | X | X |
| March | PCWP/HCPWP-Joint workshop on personalised medicines | X | X |
| March | Public-private collaborations & partnerships for vaccine benefit-risk monitoring in Europe: the ADVANCE framework and governance principles | X | X |
| March | Workshop on revising the guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicines | X | |
| March | Seventh Framework Programme (FP7) small-population research methods projects and regulatory application workshop | X | X |
| May | 2017 annual workshop of the European network of paediatric research at the European Medicines Agency (Enpr-EMA) | X | X |
| May | First anniversary of PRIME: experience so far | X | |
| June | Joint workshop addressing unmet needs of children with pulmonary arterial hypertension (PAH) | X | X |
| June | Cystic fibrosis workshop - Registries initiative | X | |
| July | Multiple Sclerosis (MS) Registries – Workshop | X | |
| September | Payer Community meeting | X | |
| September | PCWP and HCWP joint meeting: info session on antimicrobial resistance (AMR) | X | X |
| September | Eleventh stakeholder forum on the pharmacovigilance legislation | X | X |
| September | Interested Parties meeting with the Biosimilar Medicinal Products Working Party | X | X |
| October | EU clinical trials portal and Union database meeting with Stakeholders | X | X |
| October | Joint Drug Information Association (DIA) / European Forum for Good Clinical Practice (EFGCP) /European Medicines Agency (EMA) conference on how to optimise children's access to innovative medicines | X | |
| November | Second paediatric strategy forum on medicine development for mature B cell malignancies in children | X | X |
| November | EMA/DIA information day on measuring the impact of pharmacovigilance activities | X | X |
| December | Data anonymisation workshop | X | X |
| December | A common data model in Europe? – Why? Which? How? | X | X |
| December | Workshop on site and histology - Independent indications in oncology | X | X |

Annex V: Participation in EMA Workshops (2009-2017)

A: Patients

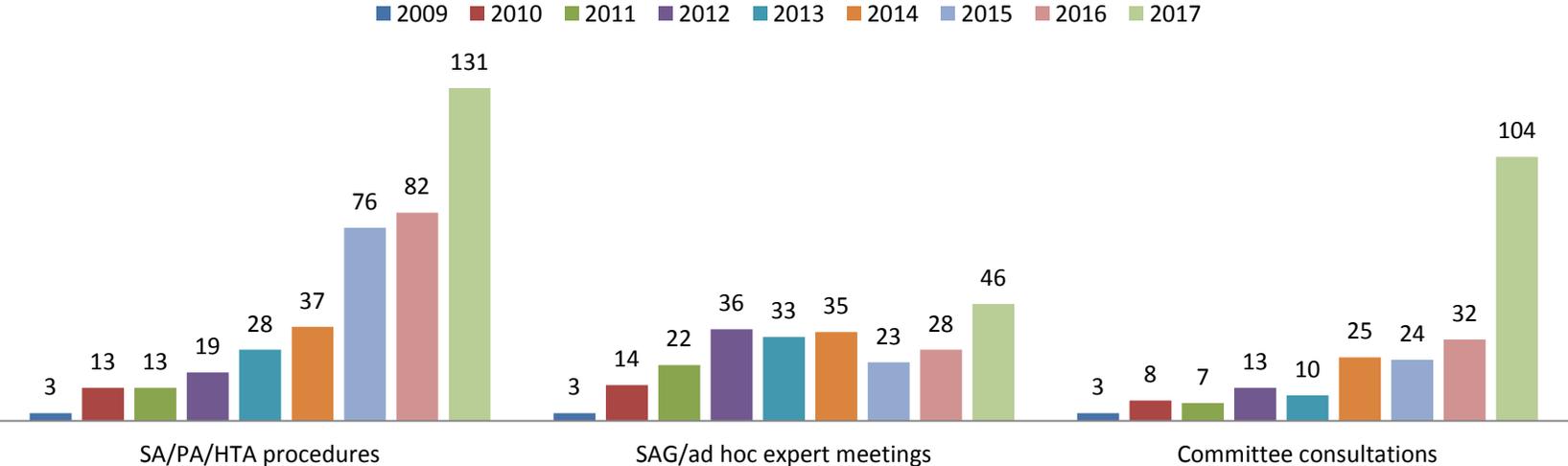


B: Healthcare professionals

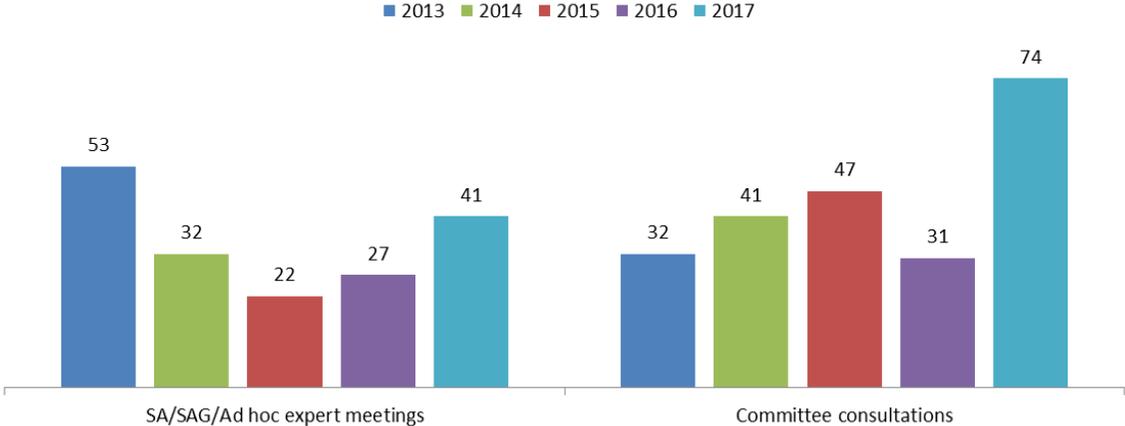


Annex VI: Patient and healthcare professional involvement in EMA activities (2009-2017)

A: Patients

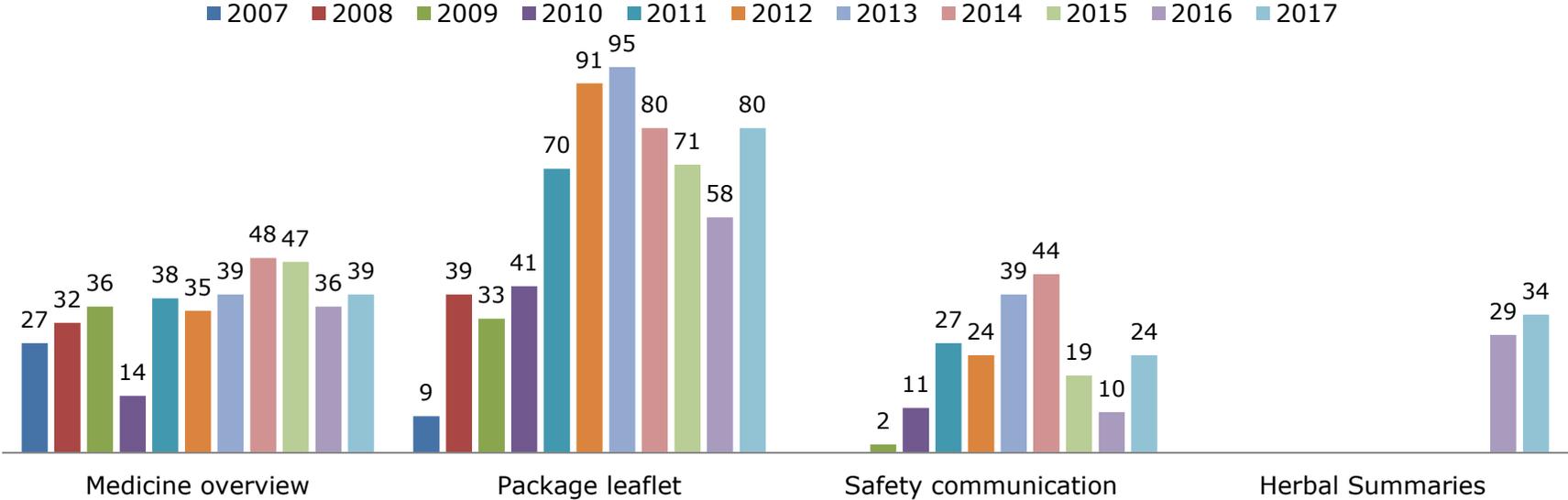


B: Healthcare professionals

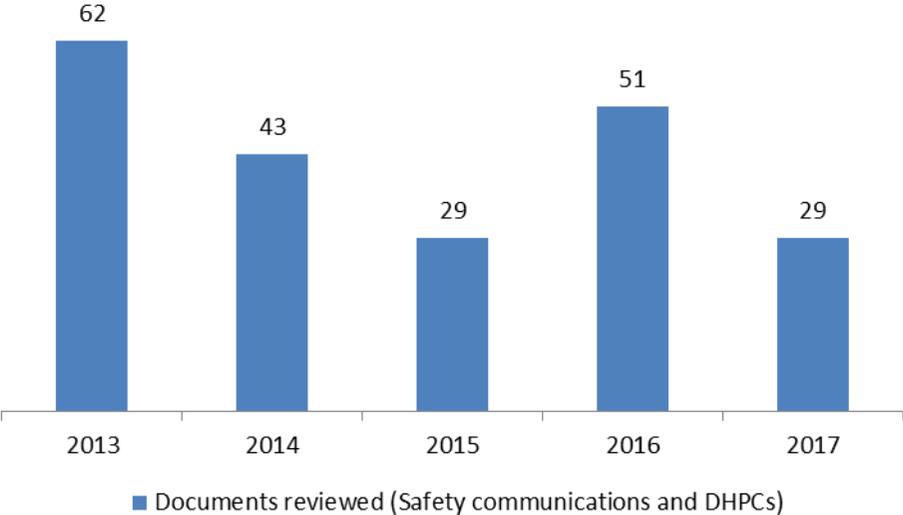


Annex VII: Documents reviewed (2007-2017) by patients and healthcare professionals

A: Patients



B: Healthcare professionals



Annex VIII: Eligible organisations working with EMA

A: Patient and Consumer organisations

| | |
|----|--|
| 1 | AGE Platform Europe (AGE) |
| 2 | Alzheimer Europe (AE) |
| 3 | Debra International |
| 4 | European AIDS Treatment Group (EATG) |
| 5 | European Cancer Patient Coalition (ECPC) |
| 6 | European Federation of Allergy and Airways Diseases Patients' Associations (EFA) |
| 7 | European Federation of Neurological Associations (EFNA) |
| 8 | European Foundation for the Care of Newborn Infants (EFCNI) |
| 9 | European Gaucher Alliance (EGA) |
| 10 | European Genetic Alliances' Network (EGAN) |
| 11 | European Haemophilia Consortium (EHC) |
| 12 | European Headache Alliance (EHA) |
| 13 | European Heart Network (EHN) |
| 14 | European Institute of Women's Health (EIWH) |
| 15 | European Liver Patient Association (ELPA) |
| 16 | European Multiple Sclerosis Platform (EMSP) |
| 17 | European Network of Fibromyalgia Associations (ENFA) |
| 18 | European Organisation for Rare Diseases (EURORDIS) |
| 19 | European Parkinson's Disease Association (EPDA) |
| 20 | European Patients' Forum (EPF) |
| 21 | European Prostate Cancer Coalition (EUomo) |
| 22 | European Public Health Alliance (EPHA) |
| 23 | Fabry International Network (FIN) |
| 24 | Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe) |
| 25 | Health Action International (HAI) |
| 26 | International Alliance of Patients' Organizations (IAPO) |
| 27 | International Bureau of Epilepsy (IBE) |
| 28 | International Diabetes Federation European Region (IDF Europe) |
| 29 | International Patient Organisation for Primary Immunodeficiencies (IPOPI) |
| 30 | Myeloma Patients Europe (MPE) |
| 31 | Pain Alliance Europe (PAE) |
| 32 | Spinal Muscular Atrophy Europe (SMAE) |
| 33 | Thalassaemia International Federation (TIF) |
| 34 | The European Consumers' Organisation (BEUC) |
| 35 | United Parent Projects Muscular Dystrophy (UPPMD) |

B: Healthcare professional organisations

| | |
|----|---|
| 1 | European Academy of Allergy and Clinical Immunology (EAACI) |
| 2 | European Academy of Paediatrics (EAP) |
| 3 | European Academy of Neurology (EAN) |
| 4 | European Association for Clinical Pharmacology and Therapeutics (EACPT) |
| 5 | European Association of Hospital Pharmacists (EAHP) |
| 6 | European Association for the Study of Diabetes (EASD) |
| 7 | European Association of Urology (EAU) |
| 8 | European College of Neuropsychopharmacology (ECNP) |
| 9 | European Federation of Internal Medicine (EFIM) |
| 10 | European Forum for Primary Care (EFPC) |
| 11 | European Haematology Association (EHA) |
| 12 | European League Against Rheumatism (EULAR) |
| 13 | European Headache Federation (EHF) |
| 14 | European Renal Best Practice (ERBP) |
| 15 | European Respiratory Society (ERS) |
| 16 | European Society of Cardiology (ESC) |
| 17 | European Society of Endocrinology (ESE) |
| 18 | European Society for Medical Oncology (ESMO) |
| 19 | European Specialist Nurses Organisations (ESNO) |
| 20 | European Society of Oncology Pharmacy (ESOP) |
| 21 | European Society of Radiology (ESR) |
| 22 | European Union of General Practitioners / Family physicians (UEMO) |
| 23 | European Union Geriatric Medicine Society (EUGMS) |
| 24 | European Working Group on Gaucher Disease (EWGGD) |
| 25 | Health Care Without Harm Europe (HCWH Europe) |
| 26 | International League Against Epilepsy (ILAE) |
| 27 | Pharmaceutical Group of the European Union (PGEU) |
| 28 | Standing Committee of European Doctors (CPME) |
| 29 | United European Gastroenterology (UEG) |