



Report of EFA training for patient experts on allergy, asthma and COPD on getting involved with the European Medicines Agency (EMA)

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is a non-profit network of allergy, asthma and chronic obstructive pulmonary disease (COPD) patients' organisations, representing 35 national associations in 22 countries and over 400,000 patients. EFA is dedicated to making Europe a place where people with allergies, asthma and COPD have the right to best quality of care and safe environment, live uncompromised lives and are actively involved in all decisions influencing their health. www.efanet.org



This report arises from EFA operational programme 2014, which has received funding from the European Union in the framework of the Health Programme (2008-2013). The content of this report is EFA's sole responsibility; it can in no way be taken to reflect the views of the European Commission and/or the Executive Agency for Health and Consumers or any other body of the European Union. The European Commission and/or the Executive Agency do(es) not accept responsibility for any use that may be made of the information it contains.

Introduction

On the 18th of February 2014, EFA organised its first training for patient experts on allergy, asthma and COPD on getting involved with the [European Medicines Agency \(EMA\)](#). The programme is available [here](#).

As this was the first training of this type organised by EFA, it was addressed to beginners. 15 patient experts (13 participants + EFA President and EFA representative at EMA Patients' and Consumers' Working Party) from 10 EFA member associations had the opportunity to discover what EMA does and especially how patients can be involved in its activities. Through EFA, patient experts on allergy, asthma and COPD across Europe can be involved in the important work that EMA is doing throughout the process of evaluation, assessing and communication about medicines. EFA members learnt from the patient experts already involved with EMA, as well as from EMA secretariat itself. All presentations can be found [here](#).

As a result of the call for expression of interest sent to all EFA members, 13 members (in addition to our President Breda Flood from [Asthma Society of Ireland](#) and Board member Lina Buzermaniene from [Lithuanian Council of Asthma Clubs](#)) showed their interest in participating in the training:

1. Contreras Javier, [FENAER](#)
2. Hadzhiangelova Diana, [Association of Bulgarians with Bronchial Asthma, Allergy and COPD](#)
3. Petrov Teodor, [Association of Bulgarians with Bronchial Asthma, Allergy and COPD](#)
4. Hamerlijnck Dominique, member of the [U-BIOPRED project Patient Input Platform, Longfonds](#)
5. Kamphuis Juliette, member of the [U-BIOPRED project Patient Input Platform, Longfonds](#)
6. Kelly Niamh, [Asthma Society of Ireland](#)
7. Odemyr Mikaela, [Astma och Allergi Förbundet](#)
8. Przybysz Anna, [Polish Federation of Asthma, Allergy and COPD Patients' Organisations](#)
9. Roberts Amanda, member of the [U-BIOPRED project Patient Input Platform, Asthma UK](#) volunteer
10. Ruiz Baques Armando, [FENAER](#)
11. Salerni Giorgio, [Federasma](#)
12. Saraiva Isabel, [Respira](#)
13. Wilken Michael, [Patientenliga Atemwegserkrankungen](#)



The aim of the training was to empower EFA members to understand the role and functioning of the EMA, the role patients can play there, manage administrative issues linked to involvement and understand conflict of interest matters, with the final aim of effectively and proactively participating in EMA activities as patient experts. For this purpose, Isabelle Moulon, Head of Patients and Healthcare Professionals Department at EMA, kindly agreed to join us for the meeting and introduce the Agency as well as present possibilities of patients' involvement and the support available within its activities.

What is the European Medicines Agency?

After a tour de table to present participants, speakers and organisers, Mrs Moulon gave a comprehensive [introduction to the role of the European Medicines Agency](#) and its mission.



Isabelle Moulon, EMA

The main objective of EMA is to protect and promote public and animal health through supervision over the production of medicines in Europe. In order to reach this objective, EMA is responsible for:

- The evaluation of marketing authorisation applications for human and veterinary medicines submitted by pharmaceutical companies
- The coordination of the European pharmacovigilance (supervision of the safety of medicines on the market)
- The provision of scientific advice on the development of medicines
- The evaluation of applications for orphan designation in EU (status assigned to a medicine intended for use against a rare condition)

- The evaluation of paediatric investigation plans (or waivers) of medicines
- The evaluation of arbitration and referral procedures (used to resolve disagreements between Member States on market authorisation granting or issues as concerns over the safety or benefit-risk balance of a medicine or a class of medicines)
- The provision of good quality and independent information on the medicines it evaluates to patients and healthcare professionals
- The coordination of inspections in EU Member States' as regards the respect of Good Manufacturing Practice, Good Clinical Practice and Good Laboratory Practice (guidelines for medicines' manufacturing, clinical trials' conduct and management of laboratories' research)

How can patients be involved in EMA activities and what are the training tools available?

The active participation of patients in the process of reviewing medicines is essential for EMA.



In her second [presentation](#), Mrs Moulon explained that patients willing to take part in all EMA activities may be nominated by any patients' or consumers' organisation meeting the eligibility criteria defined by the Agency. Among others, these criteria include EU representation, legitimacy, accountability and transparency. Currently, there are 37 organisations cooperating with EMA and individual patient and consumer experts have been involved in more than 550 cases. The main platform for patients to be involved in EMA's activities is the Patients' and Consumers' Organisations Working Party ([PCWP](#)). This body provides recommendations to the Agency and its Committees on all matters of interest to patients in relation to medicinal products and serves as a platform to exchange opinions between patients and regulators. The patients are also members of:

- [Management Board](#) (MB)
- [Committee for Orphan Medicinal Products](#) (COMP)
- [Paediatric Committee](#) (PDCO)
- [Committee for Advance Therapies](#) (CAT)
- [Pharmacovigilance Risk Assessment Committee](#) (PRAC)

Among other ways of patients' involvement, there is the participation in Scientific Advisory Groups (SAGs), reviewing of information on medicines (package leaflets, etc...), involvement in EU-wide activities and many others. Mrs Moulon concluded by stressing that patient perspective is necessary to bring a unique real-life experience of the diseases.

“We do not invite patients because we have to, but because we believe that patient input is needful.”

Isabelle Moulon, EMA

To facilitate and take the most of this interaction with patients and consumers, their involvement is planned and set within a clear framework and, especially, EMA has a yearly capacity-building training for patient representatives.

Conflict of interest and the EMA

EFA’s Susanna Palkonen, who also represents the European Patients Forum (EPF), as its Vice-President, in the EMA PCWP, [presented](#) all the administrative requirements that each patient has to fill in and present before being involved with the EMA.



“The starting point is what more should I declare, not what do I have to declare?”

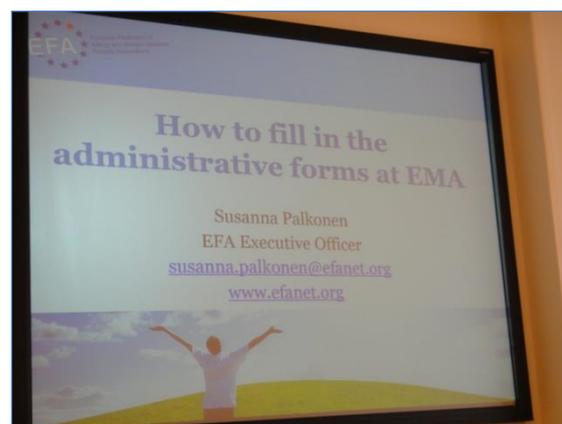
Susanna Palkonen, EFA

Patients need to be included in the [EMA expert database](#). This is done after EMA receives:

- Nomination form
- Public declaration of interests and confidentiality undertaking form

- Curriculum Vitae

The declaration of interests is being updated annually and so is the e-CV that is uploaded along with the declaration. This is to ensure that experts do not have financial or other interests in the pharmaceutical industry that could affect their impartiality.



Accordingly to the interest experts declared in the pharmaceutical industry (direct, indirect or no interest), they will have access to three levels of involvements (severely restricted, permitted, but with limitations and risk-mitigating actions or full and unrestricted).



After the presentation, each participant had the opportunity to fill in the forms on the conflict of interest with the support of EMA and EFA experts present.

Being involved in EMA information to patients

EFA Board Member Lina Buzermaniene who is for many years involved in activities of EMA as a patient expert [presented](#) on this topic.



Lina Buzermaniene, EFA

Mrs Buzermaniene explained how patients are involved in the processes of reviewing:

- [Summary of European Public Assessment Report](#) (EPAR)
- [Package leaflets for medicines](#)
- Safety communications

Patients take part in the reviewing process to ensure readability and clear understanding of the above mentioned documents, to improve the information aimed at patients for a safer use of the medicines and raise attention on unclear/missing information.



After the presentation, participants were divided into three small groups and each one reviewed information on EMA package leaflet, EPAR summary and safety communication in EFA diseases areas.

Following their experience as patients, and users of medicines, participants proved that patient input is necessary. During the process of reviewing, they pointed out unclear or misleading information within the document and proposed changes and comments that would lead to addressing all information needs, a more patient-friendly language and safer use of the medicine.

Involvement in evaluation of medicines: Scientific Advisory Group meeting case study

The [last session](#) of the day was led by EFA President Breda Flood, who is also experienced in EMA activities as a patient expert.



Breda Flood, EFA

Mrs Flood provided her example of being involved in [Scientific Advisory Group](#) (SAG) meetings, where patients provide independent recommendations on scientific or technical matters that relate to the evaluation of medicines. Their perspective provides valuable insights, such as acceptable levels of risks.



After the presentation and following discussion, participants imitated a SAG meeting and gave their opinion based on their personal experience of living with the disease regarding the example of an authorised medicine as if it was under evaluation. The discussion was very

enriching and ended the very successful day.

Conclusion and acknowledgments

The whole training was conducted in a very friendly atmosphere and despite the fact that many of the participants met each other for the first time, they were cooperating directly.

We would not be able to facilitate this training without kind participation of Mrs Moulon who found her time to come to Brussels from the EMA headquarters in London.

All the participants were largely satisfied with both content and execution of the training, but provided useful recommendations for EFA in developing further trainings. Their proactive approach was essential for all the sessions of the day. The evaluation report with participants' comments and suggestion is annexed to this report.

We are looking forward to further cooperation between the participants and the European Medicines Agency. EFA will follow up with participants to become active patient experts in EMA database.

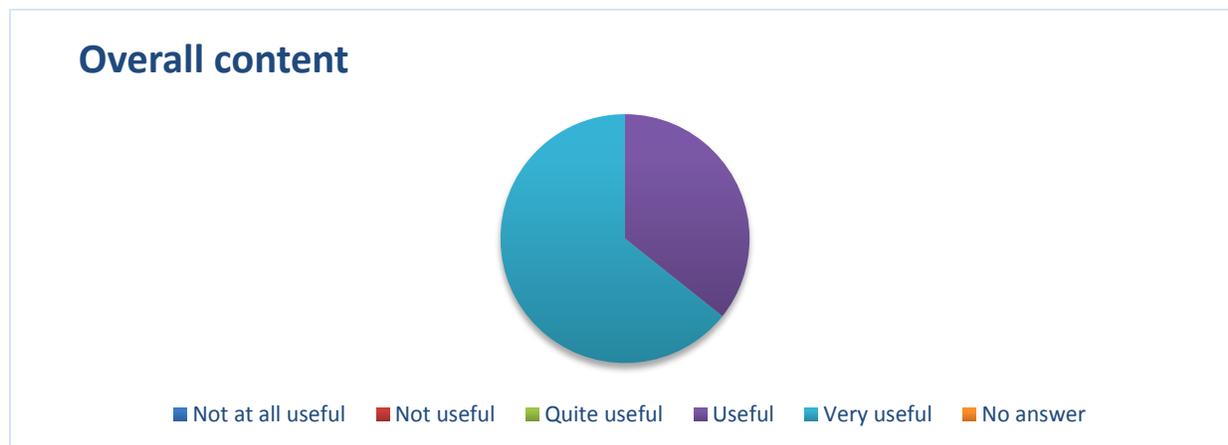
A full gallery with the pictures of the training can be found [here](#) at EFA Facebook profile.

Annex: Evaluation report

EFA members were asked to fill in evaluation forms, and on the basis of their responses, the following conclusions were drawn. We were pleased to see that all attendees submitted their evaluation forms.

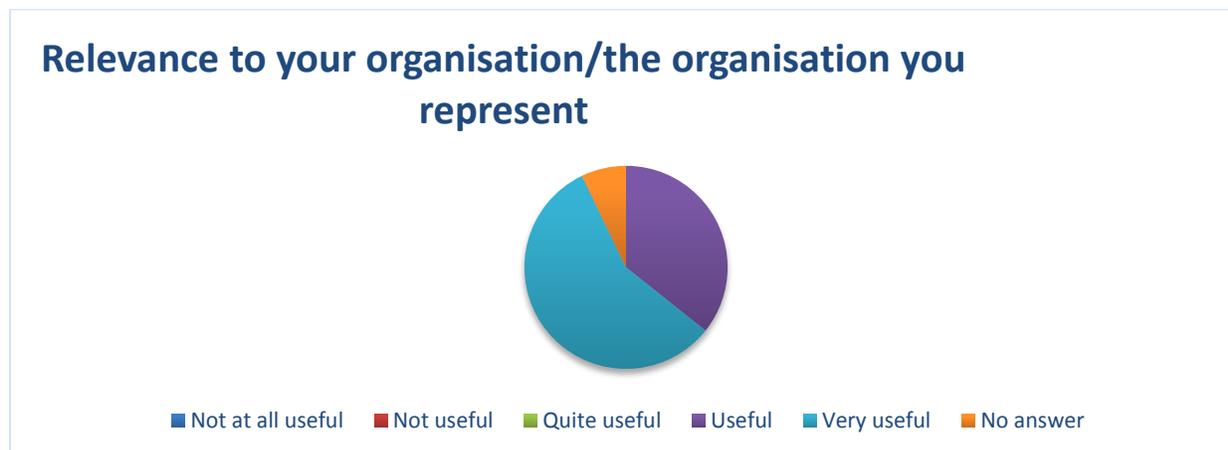
1. How did you find the following? Rate from 1 = not at all useful to 5 = very useful

a) Overall content



All participants were satisfied with the overall content of the training, 64% of them giving the highest possible rate.

b) Relevance to your organisation/the organisation you represent



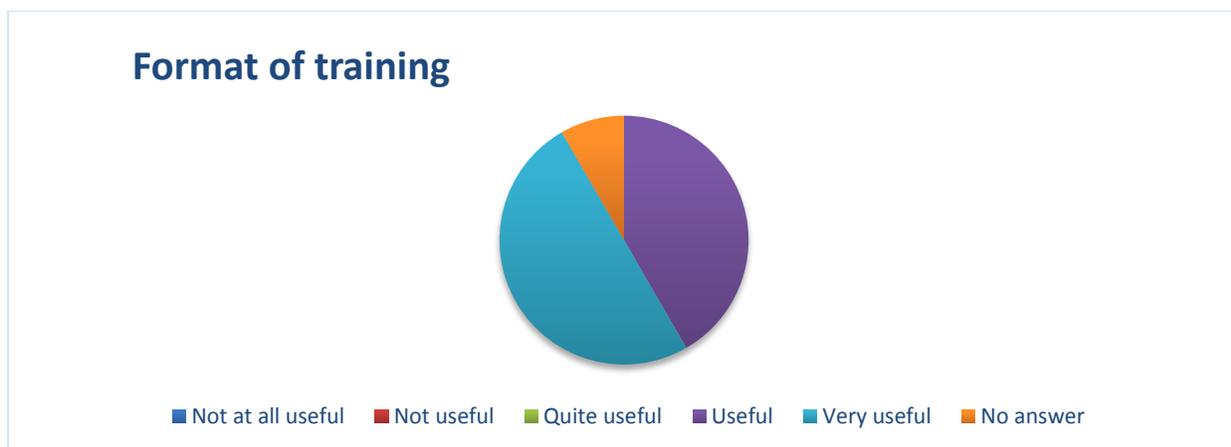
Concerning the relevance of the training to our members' organisations/the organisations they represent as volunteer, the majority (57%) of attendees considered it very useful.

c) Usefulness to your work/volunteer role



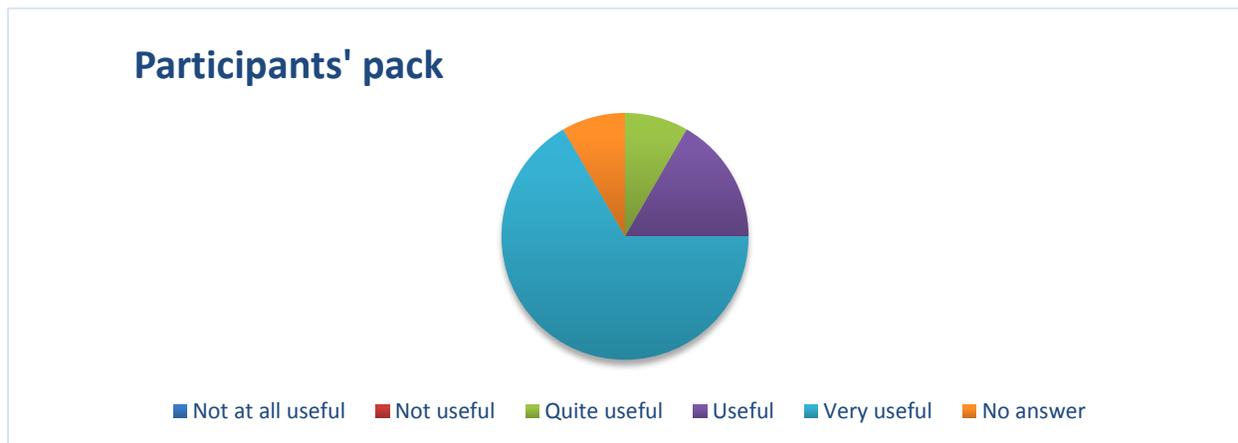
In this case, the responses were more variegated, but all participants considered the training to be useful to their work or volunteer role, 64% of them rating it as very useful.

d) Format of training



The vast majority of the participants (92%) were content or very content with the format of the training.

e) Participants' pack

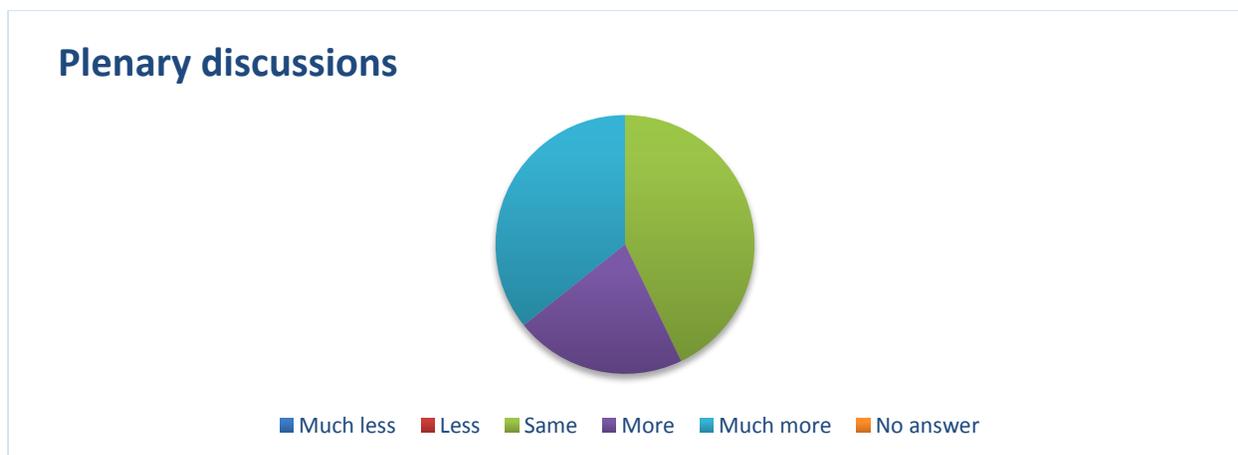


All respondents were satisfied with the participants' pack, 67% of them considered the materials provided very useful.

While reviewing the responses, it appeared that the vast majority of attendees were thoroughly satisfied with their stay in Brussels, the usefulness of the training, the format chosen and the materials *distributed*.

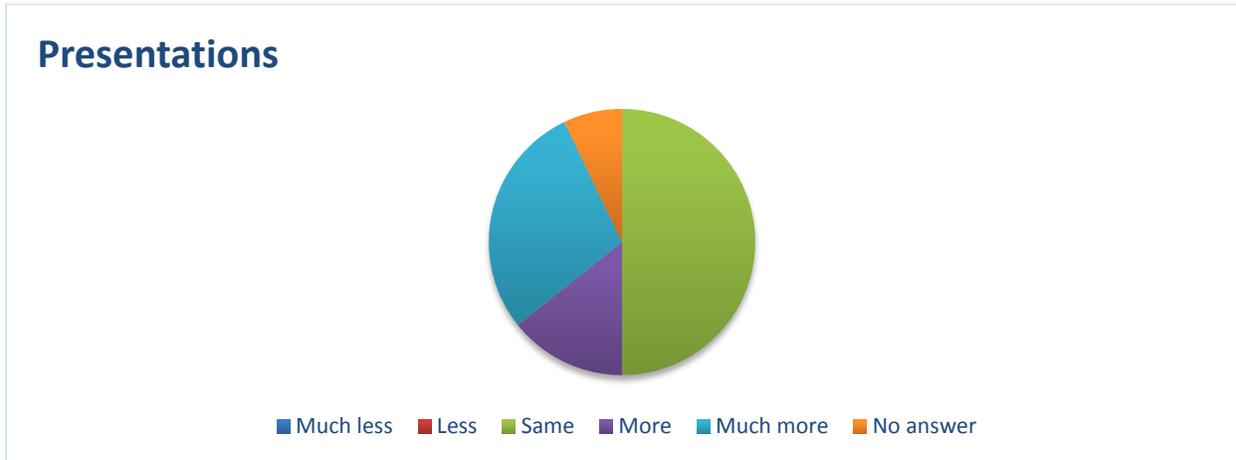
2. **Would you have liked to have more or less of the following?** Rate from 1 = much less to 5 = much more

a) Plenary discussions



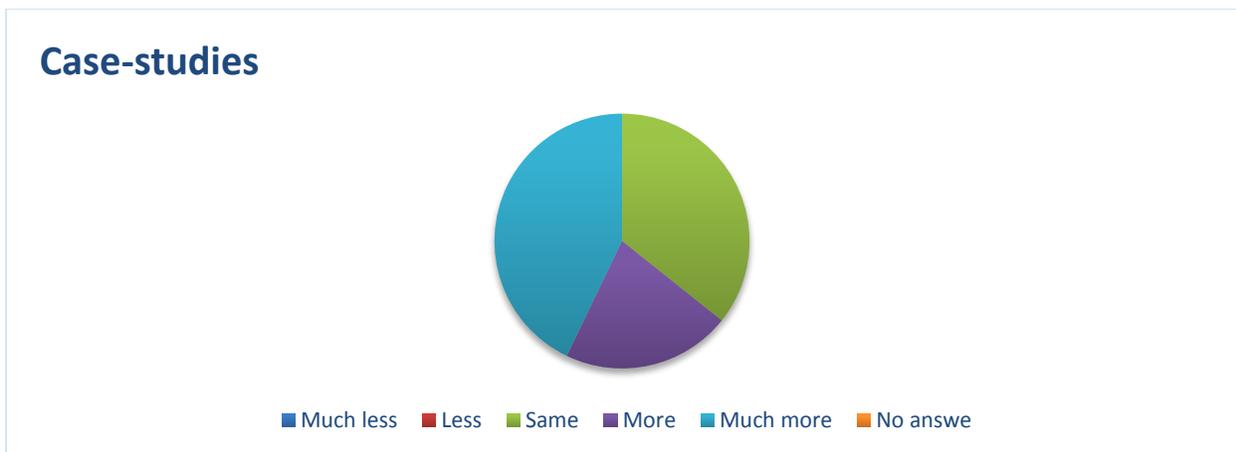
While 43% of the attendees were fully satisfied with the plenary discussions in the agenda, 57% of them would have preferred to have more or much more discussions.

b) Presentations



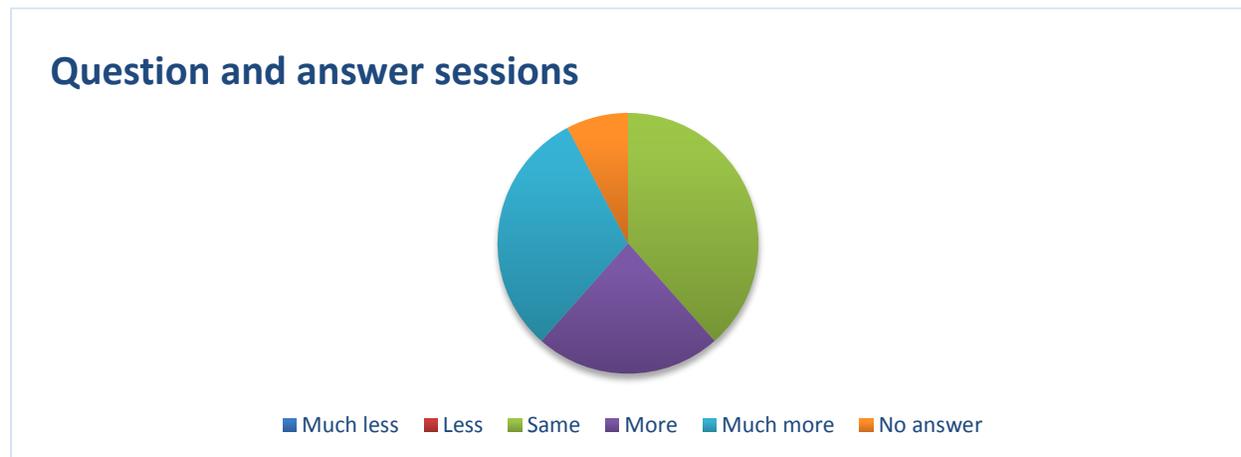
Half of the participants were happy with the number of presentations, 14% of them would have wanted more and 29% much more.

c) Case-studies



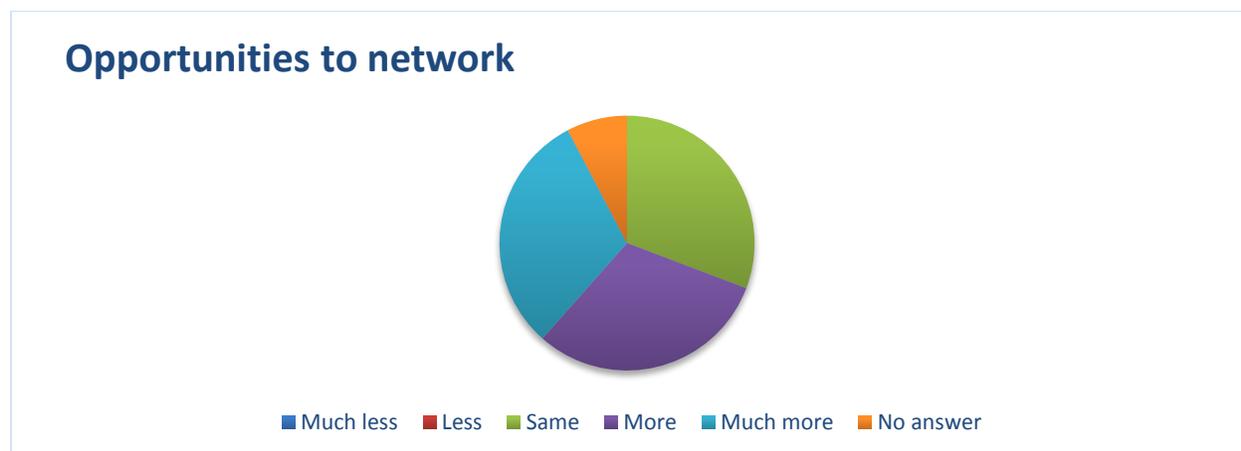
The majority of attendees (61%) wanted more or much more case-studies in next trainings of this type.

d) Question and answer sessions



Although 38% of participants were in general satisfied with their number, the majority of them (53%) would have preferred more or much more question and answer sessions.

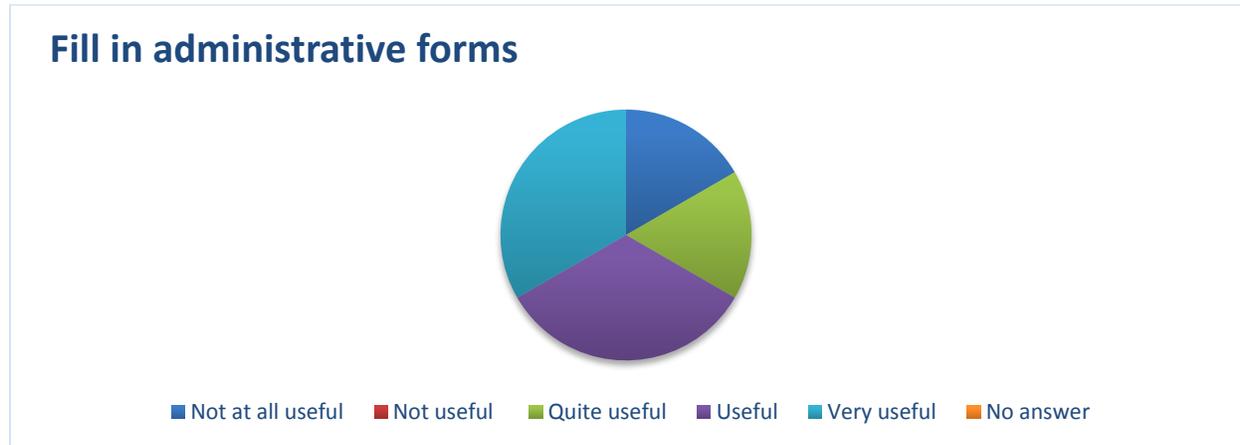
e) Opportunities to network



62% of participants stated that they would have preferred more or much more opportunities to network.

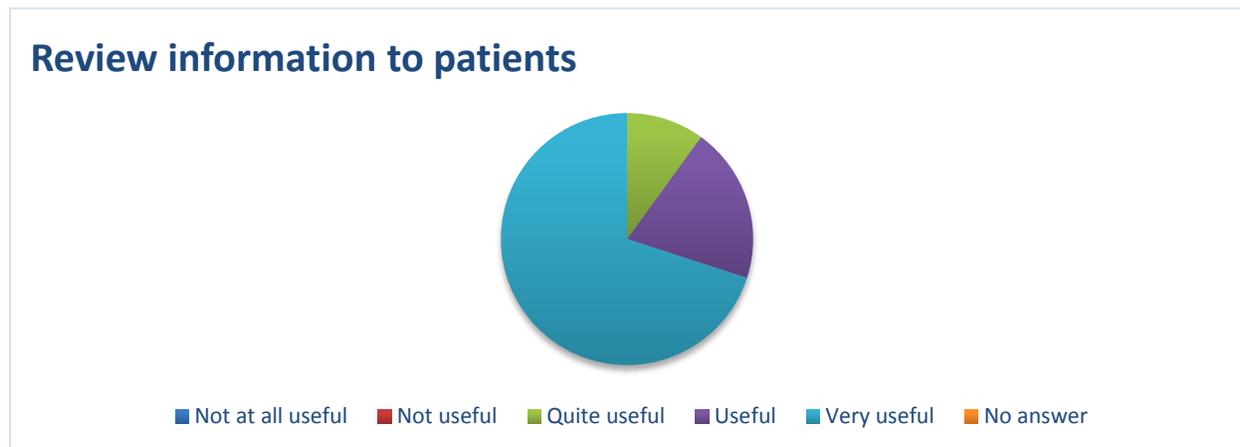
Participants were generally satisfied with the amount of presentations, case-studies, discussions, question and answer sessions and networking opportunities. They would have nonetheless preferred to have more of all of these. As a result, we could investigate the possibility to have a longer training next time that lasts one day and a half/two days.

3. **Was the training on filling the conflict of interest form worthwhile?** Rate from 1 = not at all useful to 5 = very useful



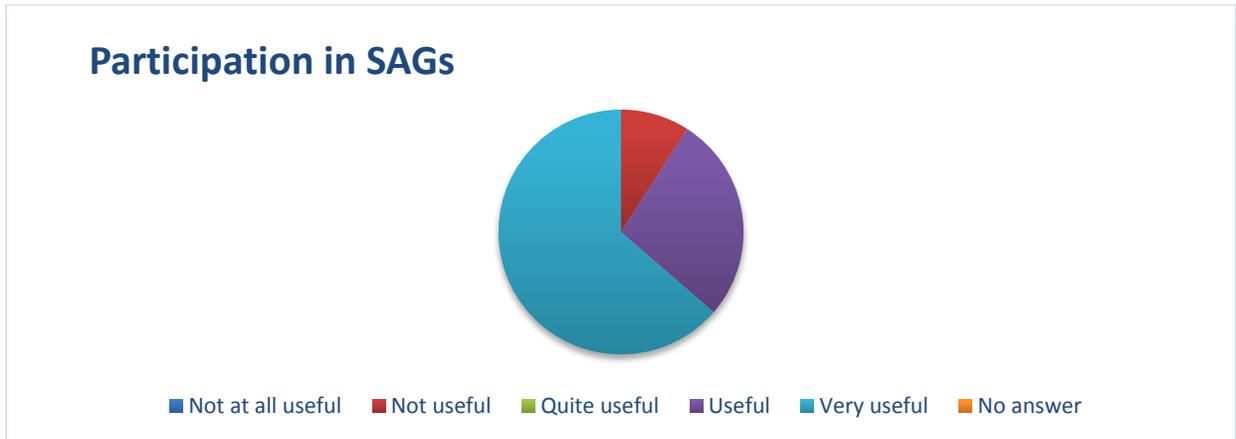
As for the training on filling in the conflict of interest form and other administrative forms, the answers were largely spread: if 33% of participants found it very useful and the same percentage useful, 17% of them defined it as quite useful and the same fraction stated that it had been not at all useful. Participants commented that the format and the explanations were useful not to confuse them while filling in the forms.

4. **Was the case-study on reviewing the information to patients worthwhile?** Rate from 1 = not at all useful to 5 = very useful



The totality of participants found the case-study on reviewing the information to patients useful, 70% of them giving the highest possible rate to it. Especially working in small groups was really appreciated by members, although some of them felt that their contribution did not represent an added value to the discussions because of their limited experience in this field.

5. **Was the case-study on the participation in Scientific Advisory Groups (SAGs) worthwhile?** Rate from 1 = not at all useful to 5 = very useful

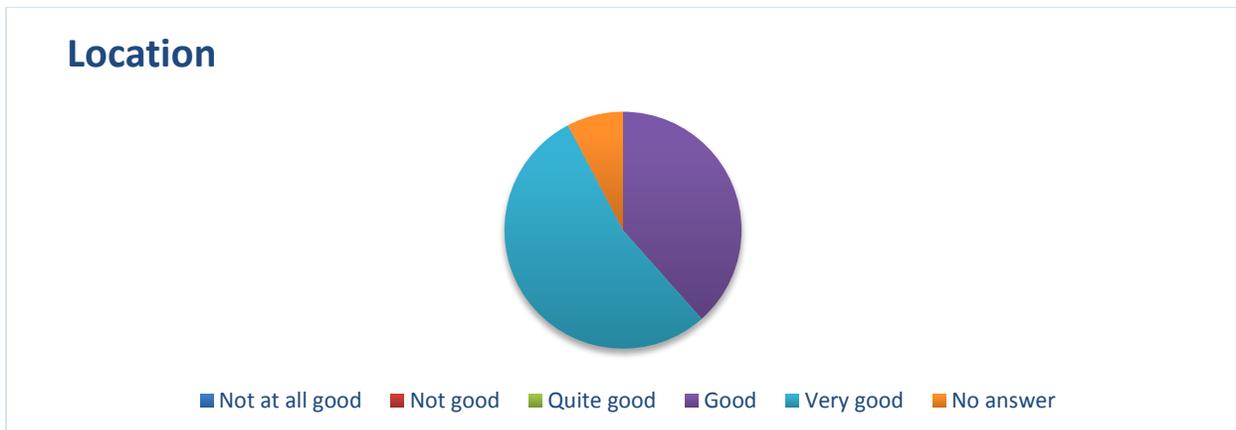


The case-study on the participation in Scientific Advisory Groups (SAGs) was considered as useful or very useful by the large majority (91%) of attendees. However, 9% of the participants rated it as not useful.

In general, people appreciated the most interactive part of the training and were satisfied with the case-studies and training given on the administrative forms. However, in some cases, negative responses were given.

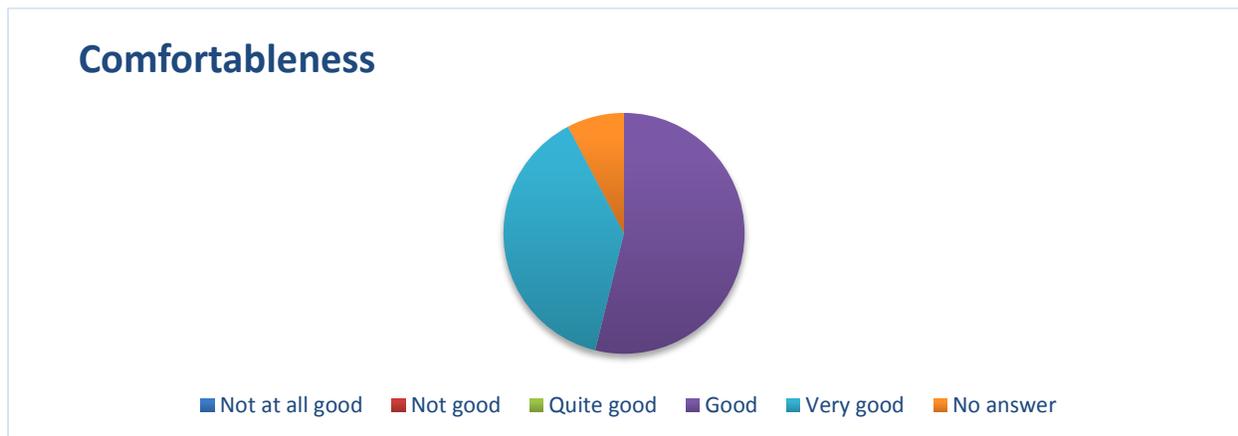
6. **How was the hotel?** Rate from 1 = not at all good to 5 = very good

- a) Location



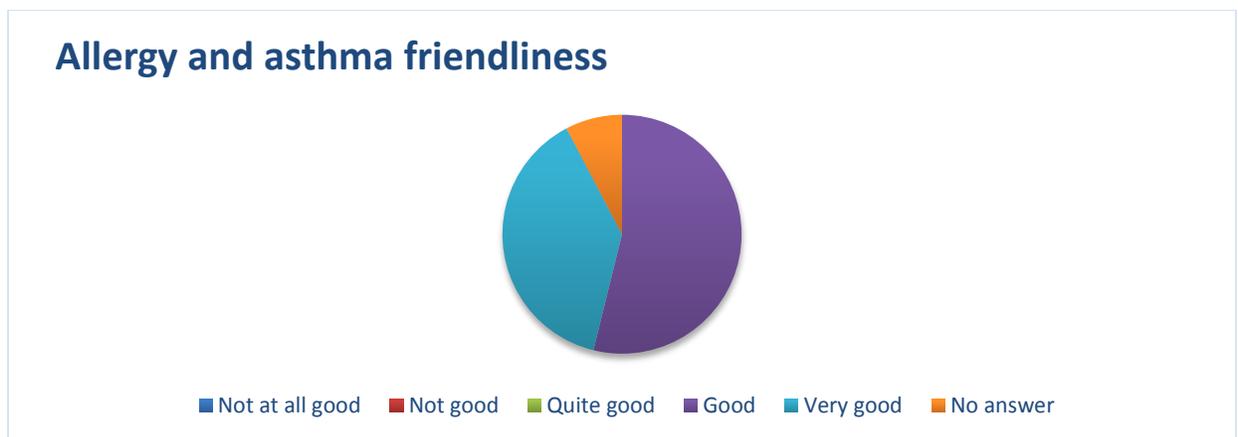
All attendees rated the location of the hotel as very good or good.

b) Comfortableness



The comfortableness of the hotel was considered as good in general.

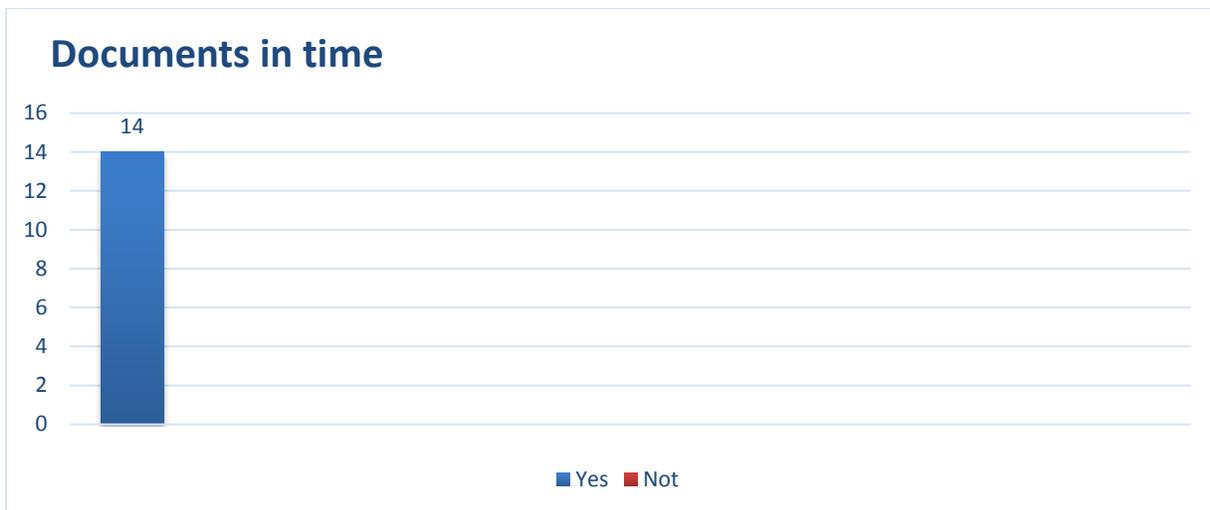
c) Allergy and asthma friendliness



The same percentage of participants (54%) rated the hotel as good for people with allergy, asthma and COPD.

The feedback regarding the hotel was positive compared with other previous accommodations EFA has used. Participants also expressed their contentment with the dinner at the restaurant the night before the training. The package (hotel + restaurant) can therefore be a suitable option for future meetings too.

7. Where the documents sent in due time? Yes or Not



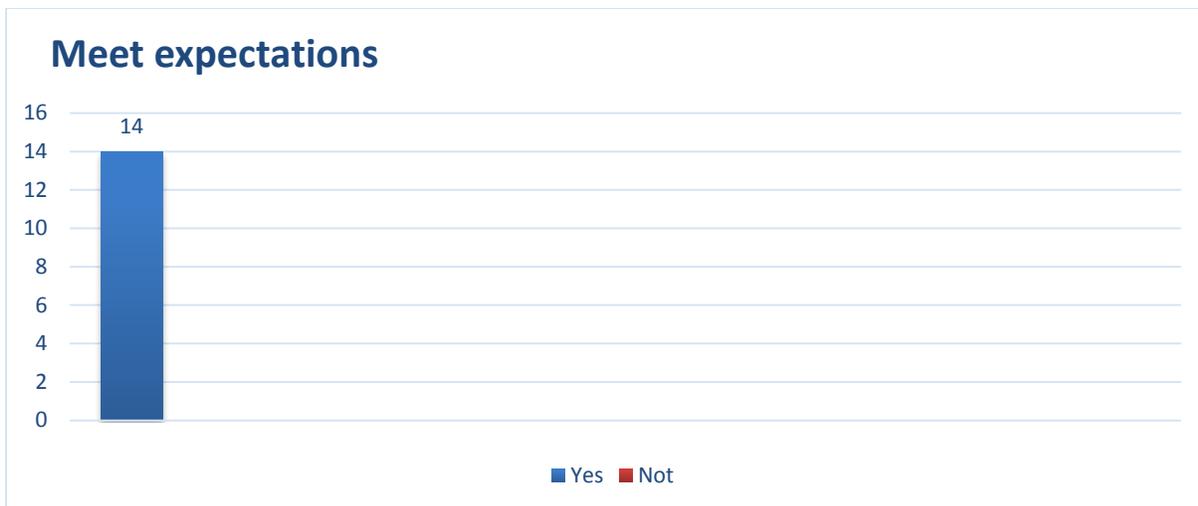
All attendees stated that documents were sent in time and they had enough time to prepare.

8. Did the training required too much preparation from your part? Yes or Not



The answer were quite spread as regards the preparation required to take part in the meeting. Indeed, if 57% of attendees responded that they did not have to prepare too much, 36% stated that the preparation required for reading the materials sent in beforehand was excessive.

9. Did the training meet your expectations and the objectives stated? Yes or Not



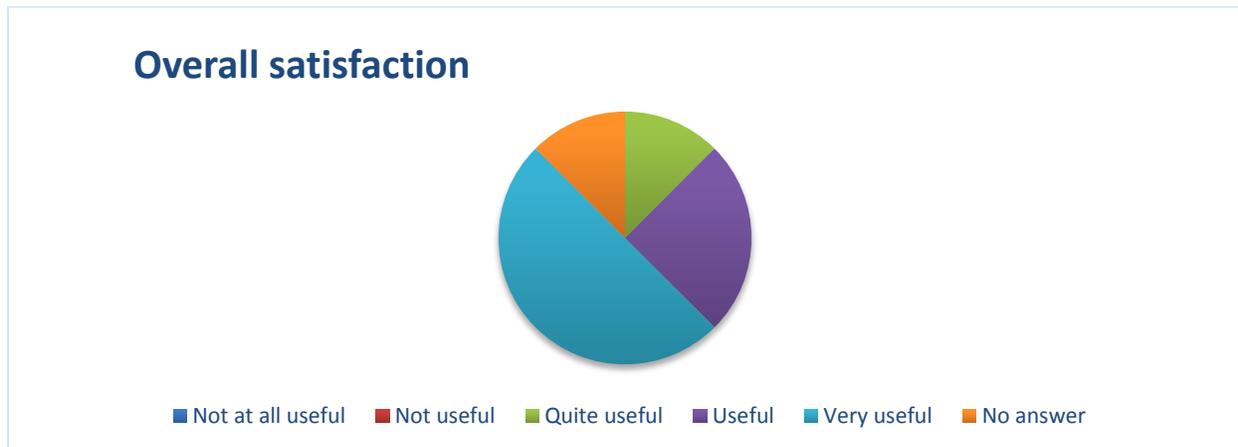
All participants were very satisfied with the training: the expectations they had before the meeting were met and the objectives of the training reached.

10. Do you feel empowered to get involved with EMA through EFA? Or do you require more training? 1 = I feel empowered, 2 = I need more training



The answers were quite spread in this case too. 43% of participants felt empowered and ready to take part in future EMA activities, 36% would require more training, while 14% would feel empowered but at the same time would welcome additional training, especially in other topics that were not touched upon during this meeting or after their initial involvement in EMA's activities and meetings.

11. **Are you overall satisfied with the training?** Rate from 1 = not at all useful to 5 = very useful



Half of the participants rated the training as very useful, the others considered it to be either useful or quite useful. The training was deemed to be very well formatted with a large amount of information delivered in a concise and easily understandable way.

Conclusions

Based on the forms collected, the following conclusions and recommendations may be drawn:

- On the whole, respondents were very pleased with their stay in Brussels. They complimented the organisers for a successful event and commented that the programme gave a good overview over EMA activities and patients' involvement. The case-studies and working in small groups, especially, were particularly appreciated.
- Some improvements were, however, suggested by members. Especially, members proposed further subjects for future trainings, such as adherence to treatment, health literacy, pricing and reimbursement of medicines. This will be followed up in the report outlining the outcomes of the policy survey for members, where priority areas for EFA's work will be defined.

EFA is considering to organise a second training that will take all these comments into account. Future trainings may present a different format and be targeted at advanced participants that have already been involved with EMA activities.