



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Performance indicator questionnaire analysis 2010

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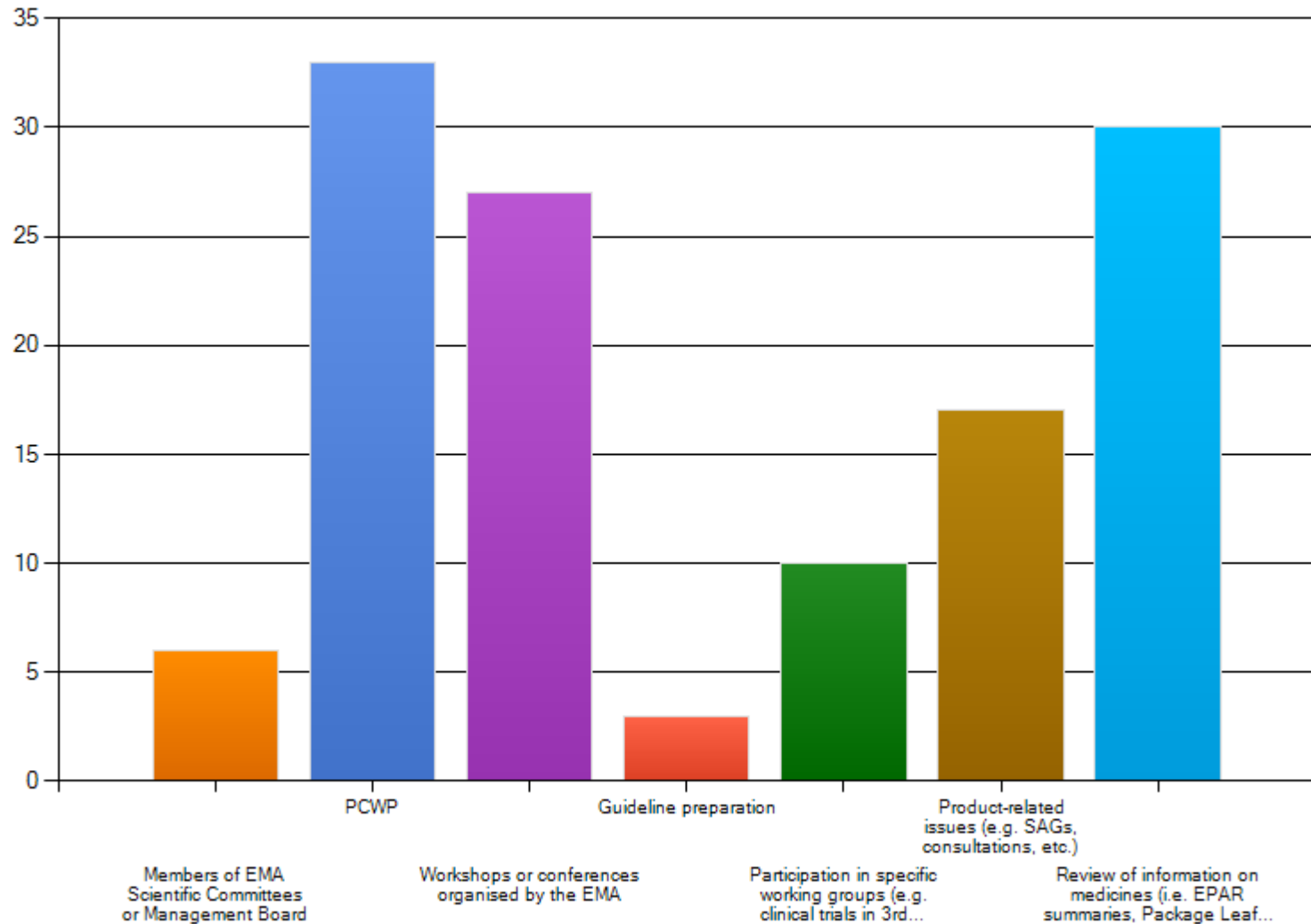


- Questionnaires sent to 132 patients/consumers
- 71 Responses received (54%) (100% from PCWP members)
- Sent to every patient/consumer who has been involved in EMA activities during 2010
- Questionnaire consists of 3 sections:
  - General interaction
  - Review of documents
  - Logistics
- Free text for detailed comments/feedback



# Activities

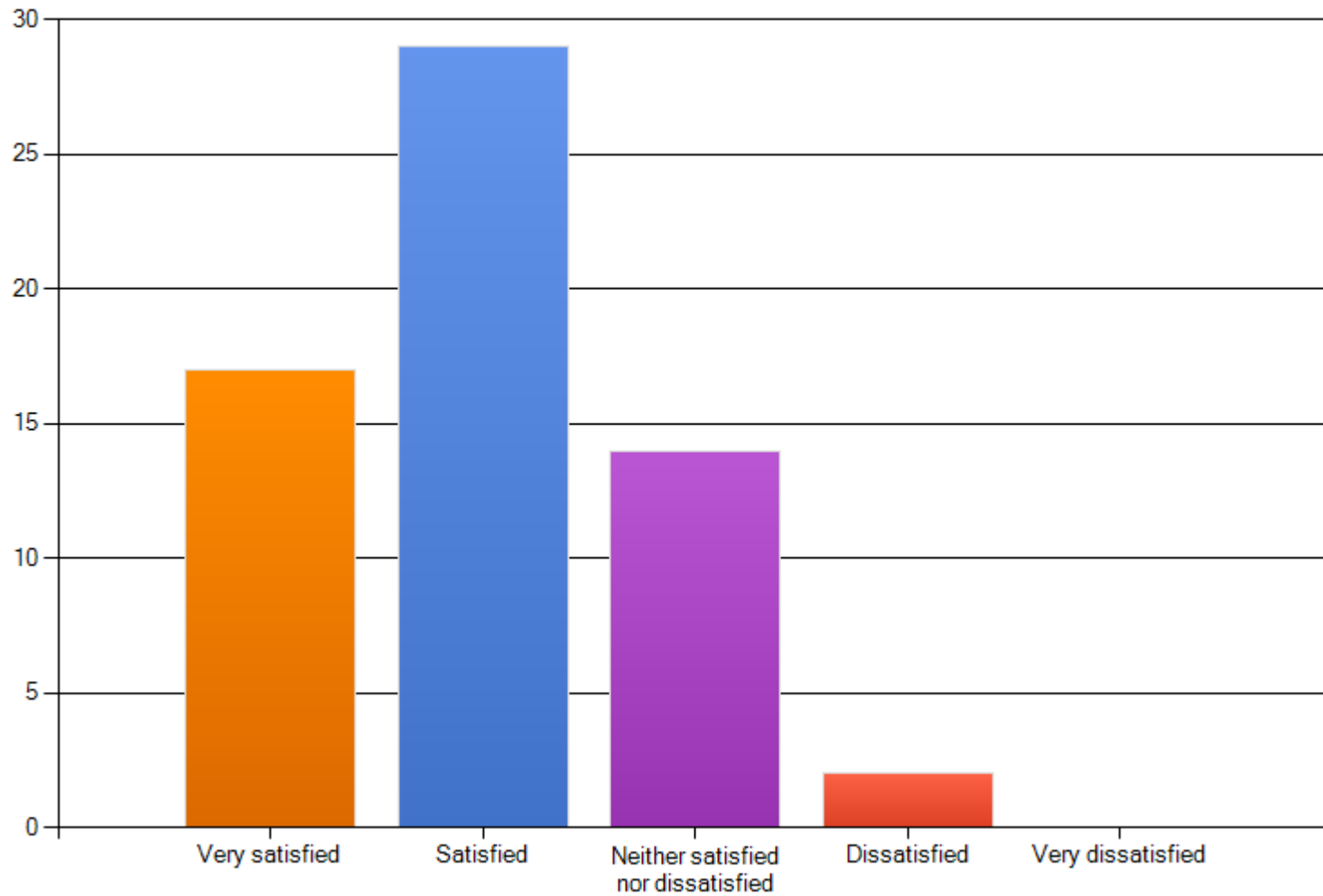
## What EMA activities have you been involved in?





# General interaction

**How do you feel overall on the interaction between the EMA and patients and consumers?**





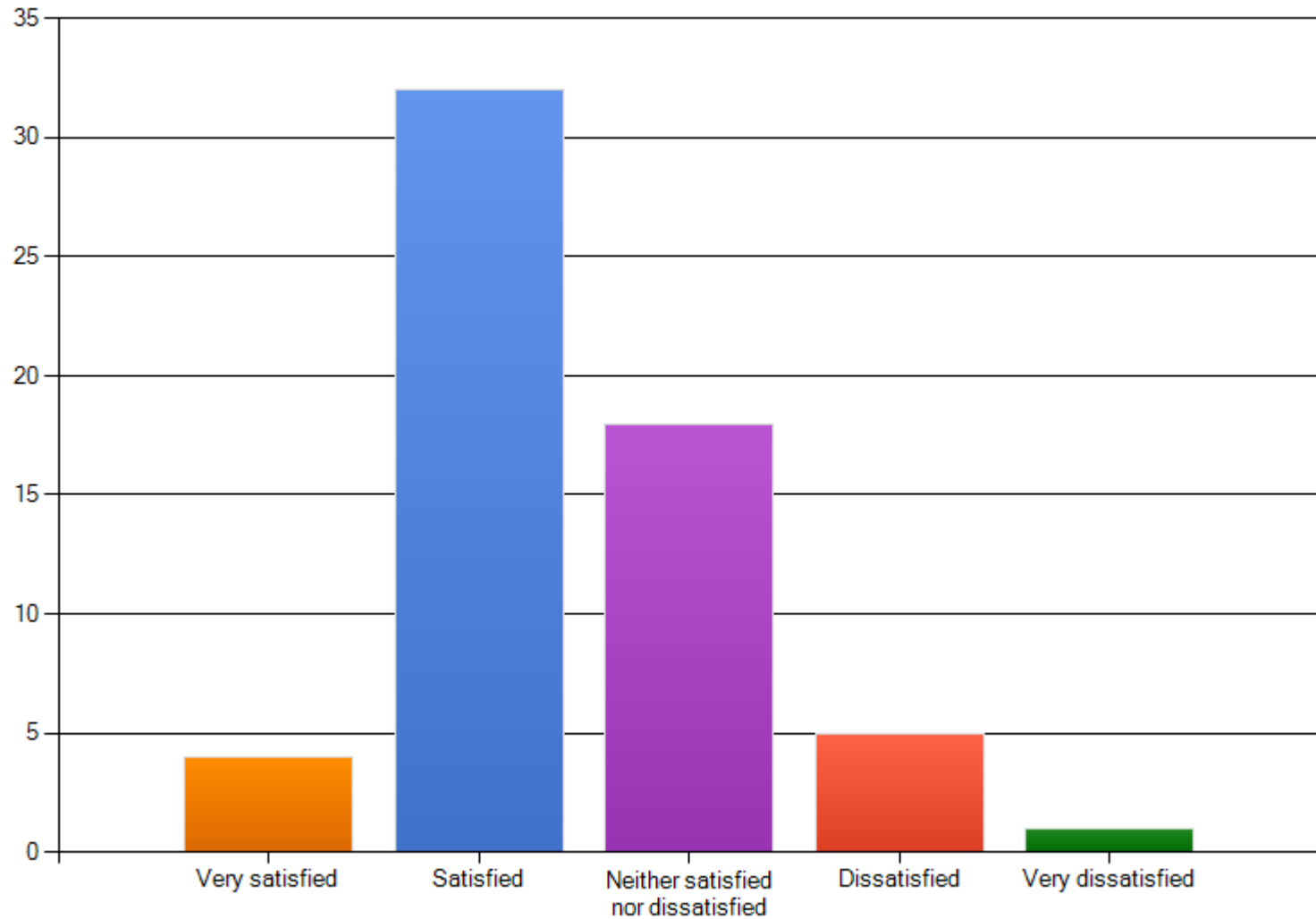
## Comments

- EMA is example for other organisations on how to include patients in a meaningful way
- NCA's could learn a lot from EMA's work with PCOs. I am very satisfied with the very ambitious work-plan and mandate of the PCWP and also of the achievements up until now
- Has improved during the last year
- Frustrating; not clear what is expected; often no response
- Worthy attempt but only partly successful
- Improvements can and should still be made
- Agency may not have full understanding on exact role of PCOs in drug development, i.e. working relations with the drug developers
- Still a long way to go



# General interaction

**Are patients and consumers adequately represented within the Agency work?**





## Comments

- Overall it is satisfactory, but in some places there can still be improvements, i.e. in the form of training for new representatives and the CHMP is not yet open for patient representatives
- The plans for further involvement are good - patients becoming equal step by step with scientific experts
- Some groups are not represented; although knowledgeable because of their "network-structure"
- Hoping for more involvement in benefit-risk evaluation and a more systematic involvement in other activities



## Comments

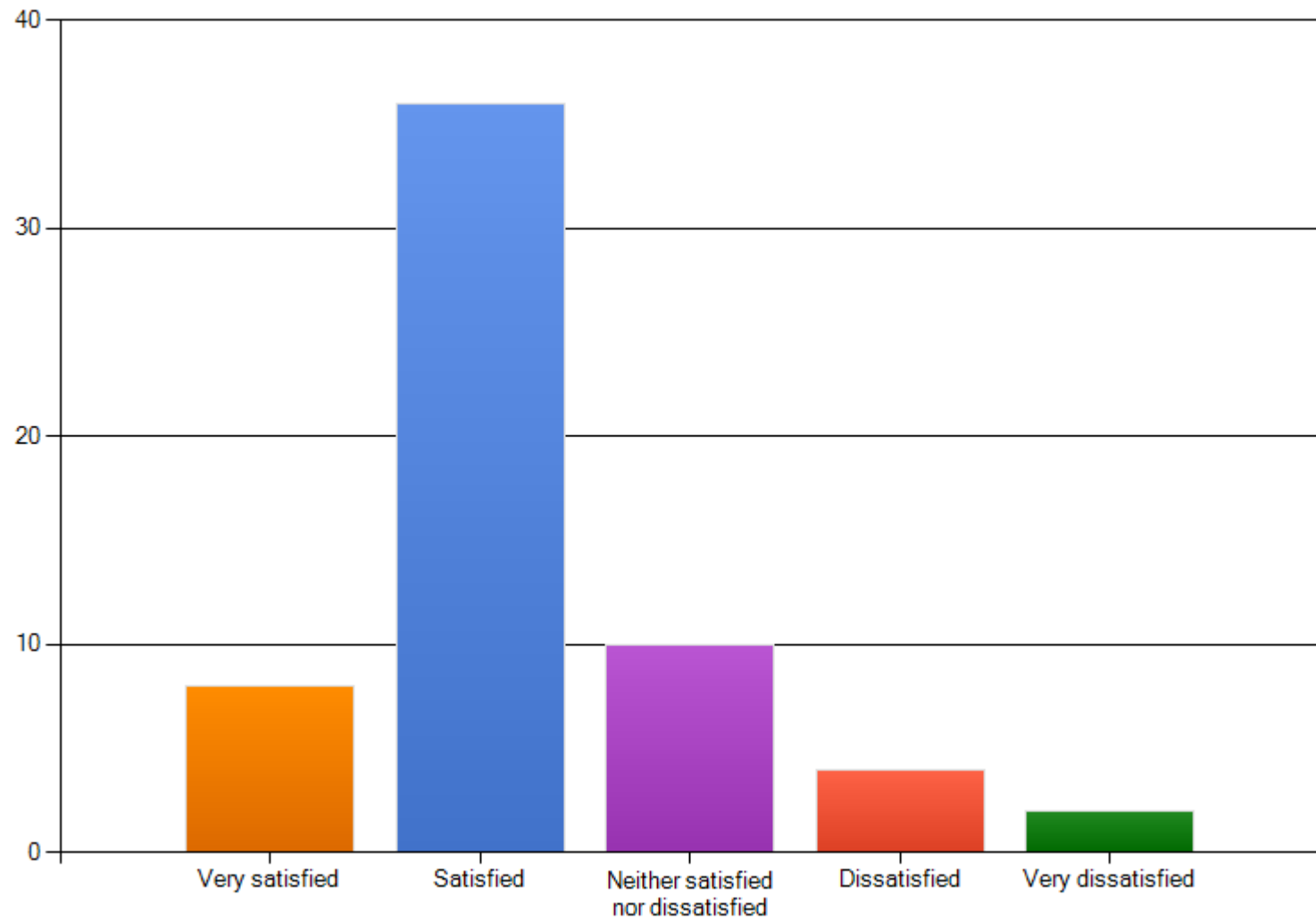
- In 2010 more PCOs have been encouraged - a very good start
- It will become more difficult with the "conflict of interest" issues
- Patient involvement and representation within the Agency work is excellent overall, BUT: A permanent representation of the patient voice within CHMP is the next logical step being overdue!
- Choice of participants inevitably narrow if made by the participating organisations
- Patients should be involved in case of urgent matters like product shortage
- Strategic areas are still under-represented





# General interaction

**Does the Agency take enough initiative to involve patients and consumers?**





## Comments

- EMA should focus on independent patient + consumers only
- Yes, but the new conflict of interest policy is an unknown factor
- Finding patient expertise from other organisations other than the patient representatives is arduous work; could be very time-consuming for the patient representative who would need even more help from the EMA-secretariat
- I feel more could and should be done to involve patients and consumers. The payment for their time is very welcome and this will encourage more people to give of their time.
- As an organisation I feel you need to reach a wider audience.



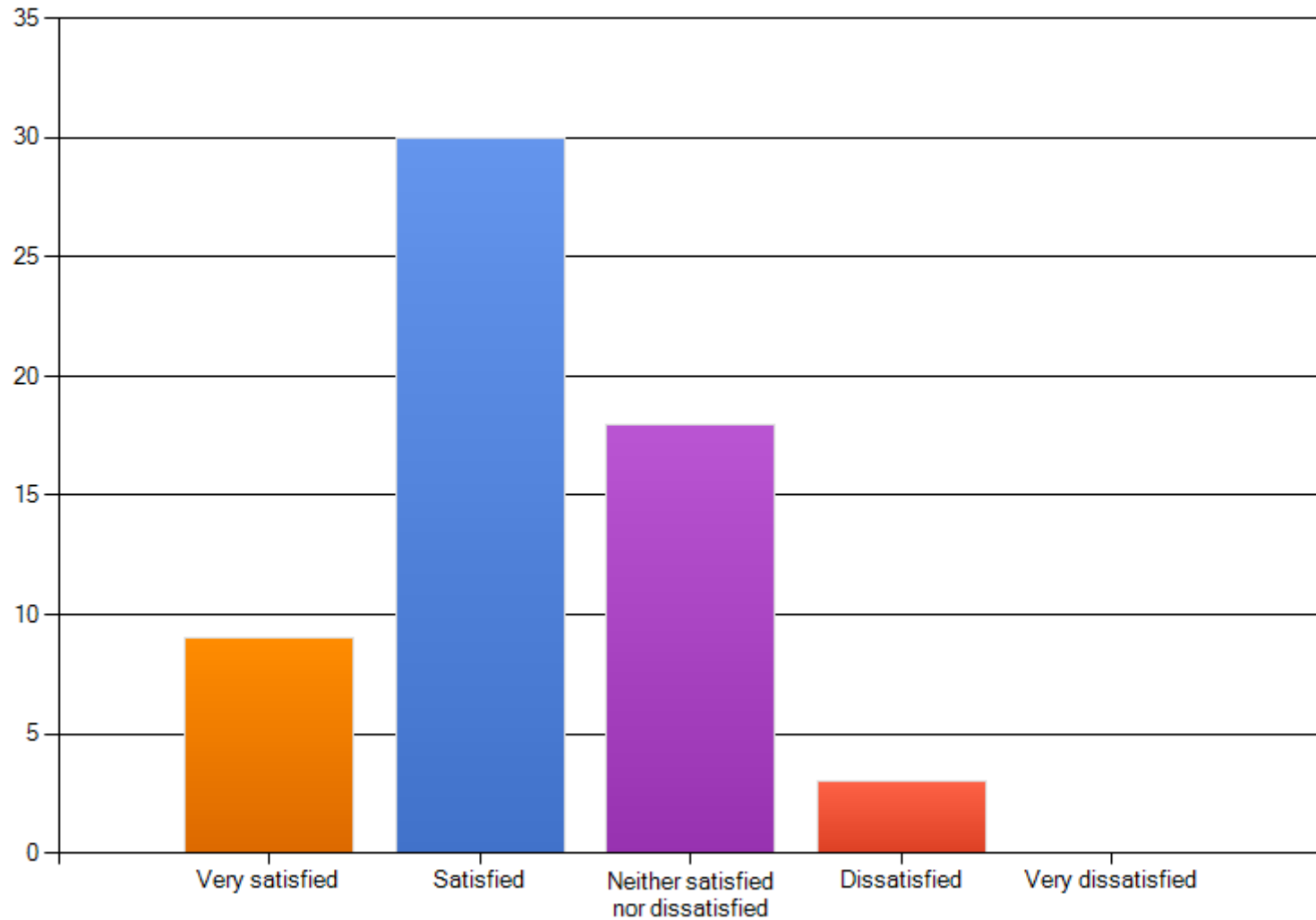
## Comments

- Maybe not enough variation in patients and consumers representatives, due to lack of human resources
- It seems more administrative than thoughtful
- The agency takes initiative but does not get really in touch with patients and consumers
- The political willingness to involve more patient representatives exists, however solutions to make this happen on a more sustainable scale may be limited (i.e. support to volunteers, greater difficulties for patient organisations to have members in the scientific committees..)



# General interaction

To what extent do you feel that your involvement has made a difference?





## Comments

- More easy to read docs, assistance with new more user friendly website
- In particular in the PhVWP and the 3rd country CT WP it is clear that the input of the perspective of patients is needed to come to the best possible decisions.  
The strength of these WP's is that this is not just understood by the patients, but also by the representatives of EMA and the NCA's
- I feel that the patients and consumers give the Agency a different perspective and can inform the Agency exactly what it is like and how they are treated as a patient. Patients and consumers bring a wealth of personal knowledge in dealing with health and social care
- By bringing an expert patient's perspective to the discussions



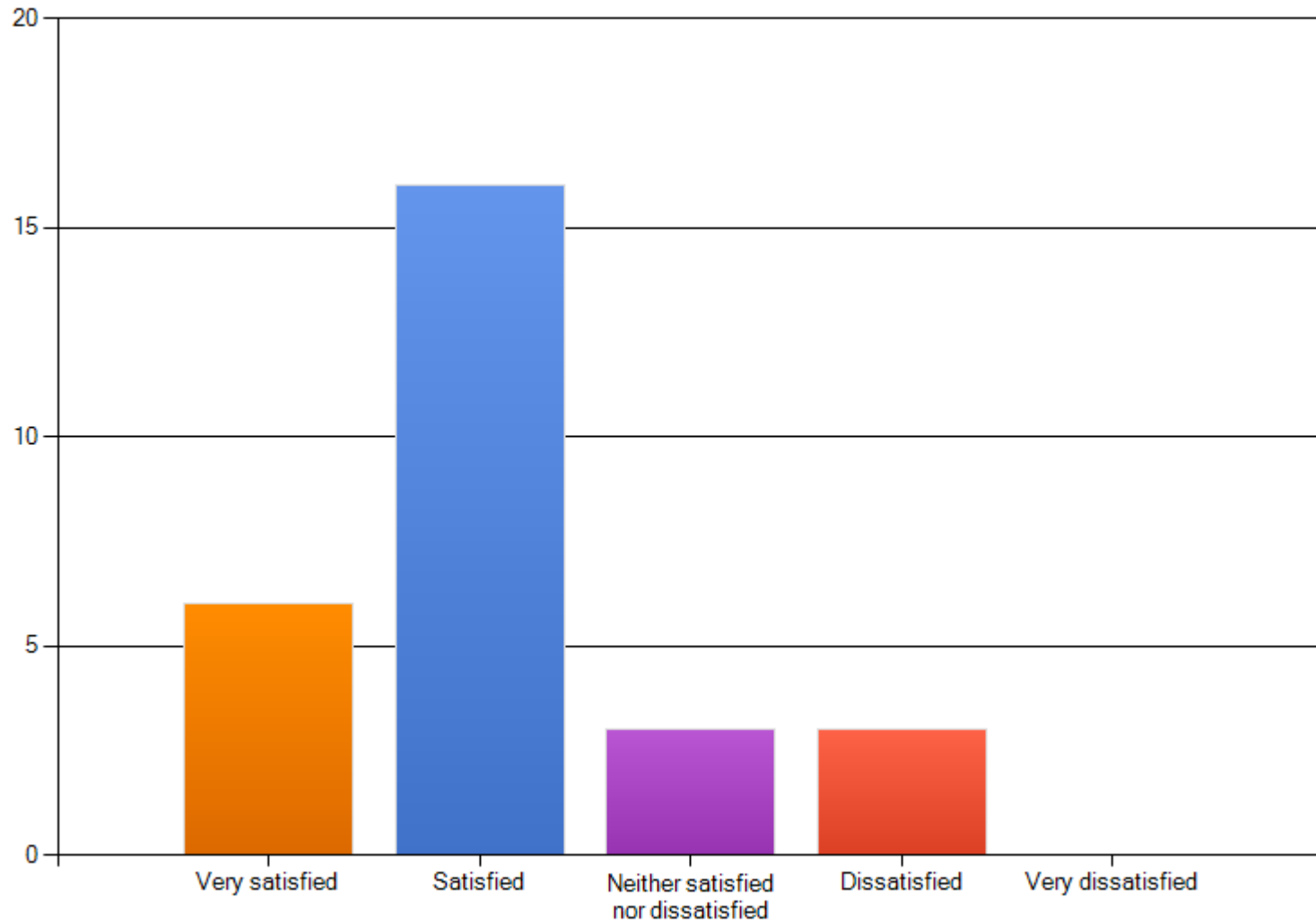
## Comments

- A very fruitful giving and taking of know-how between the Agency and patient representatives
- It was 1st time and only for 1 day, couldn't make big difference
- I haven't yet enough experience to comment
- I really do not know
- Not sure what difference it made
- It is hard to say
- Difficult to know if involvement has made a difference
- I'm quite new so difficult to answer
- I am still at the beginning of the learning curve



# Review of documents

The overall review procedure





## Main comment

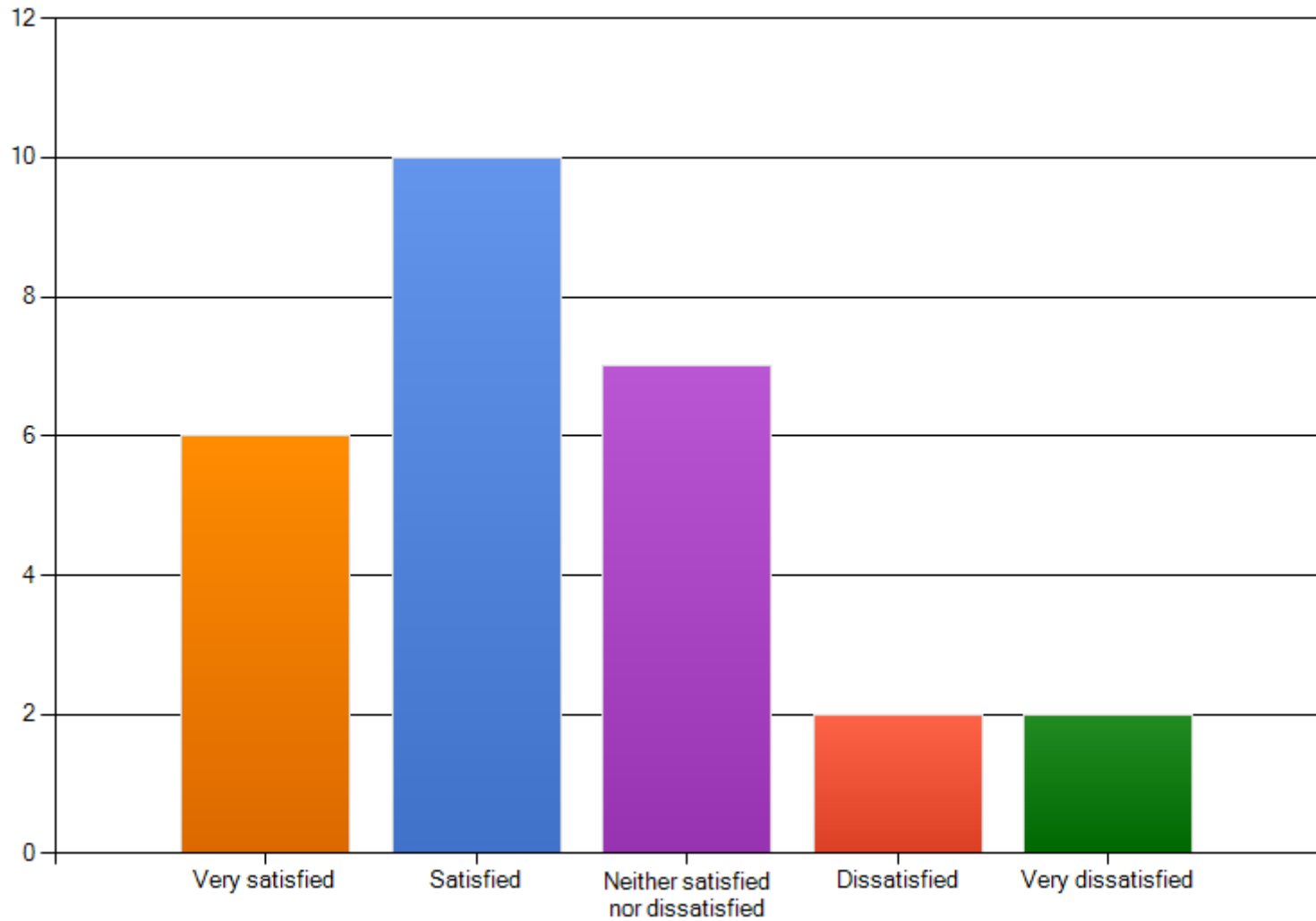
- No access to EPAR which would be needed for proper judgment





# Review of documents

The feedback you received on the documents you reviewed





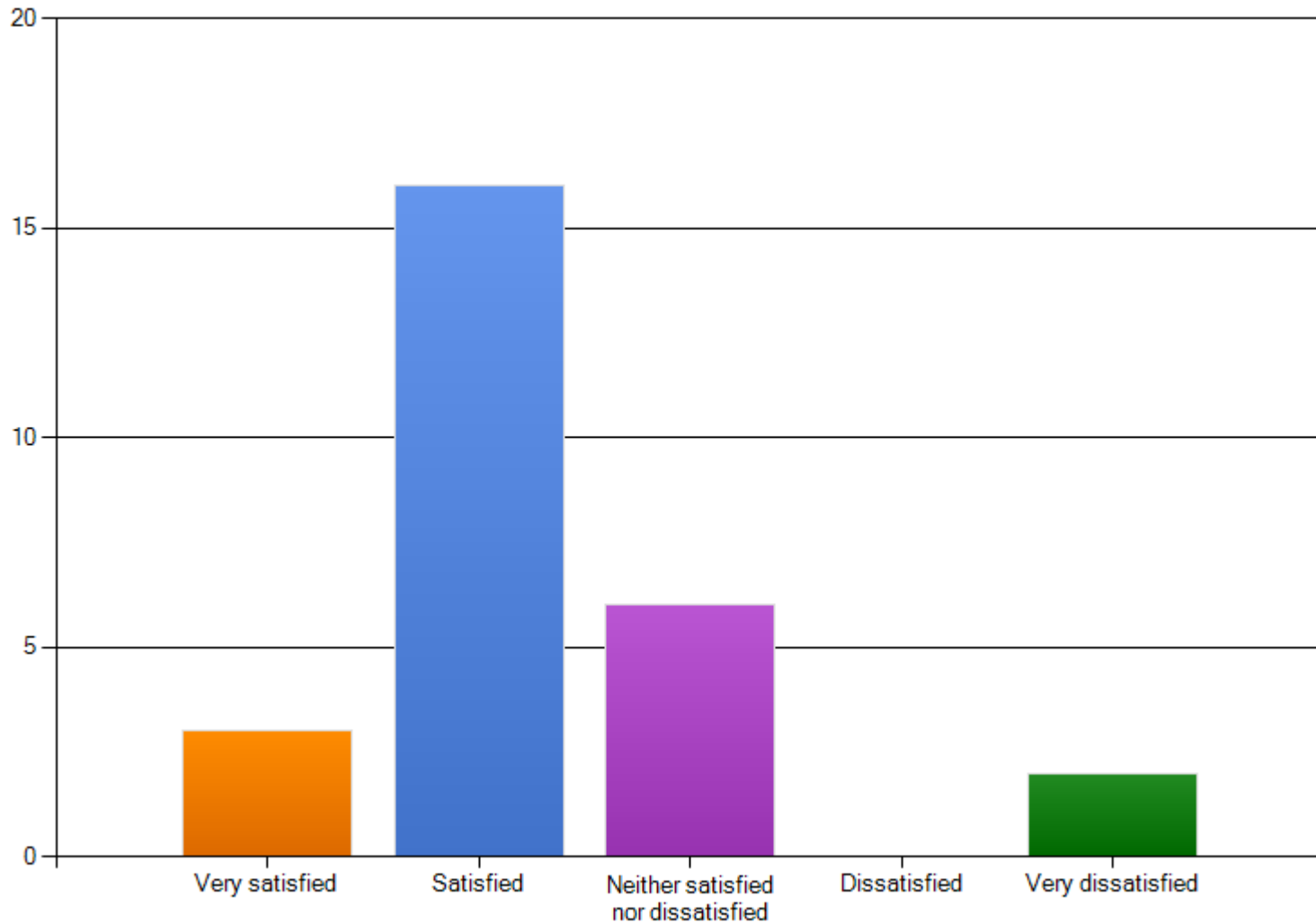
## Comments

- I feel to have received very little feedback
- No feed back
- More related to procedures than content



# Review of documents

## The impact of your work on the final documents





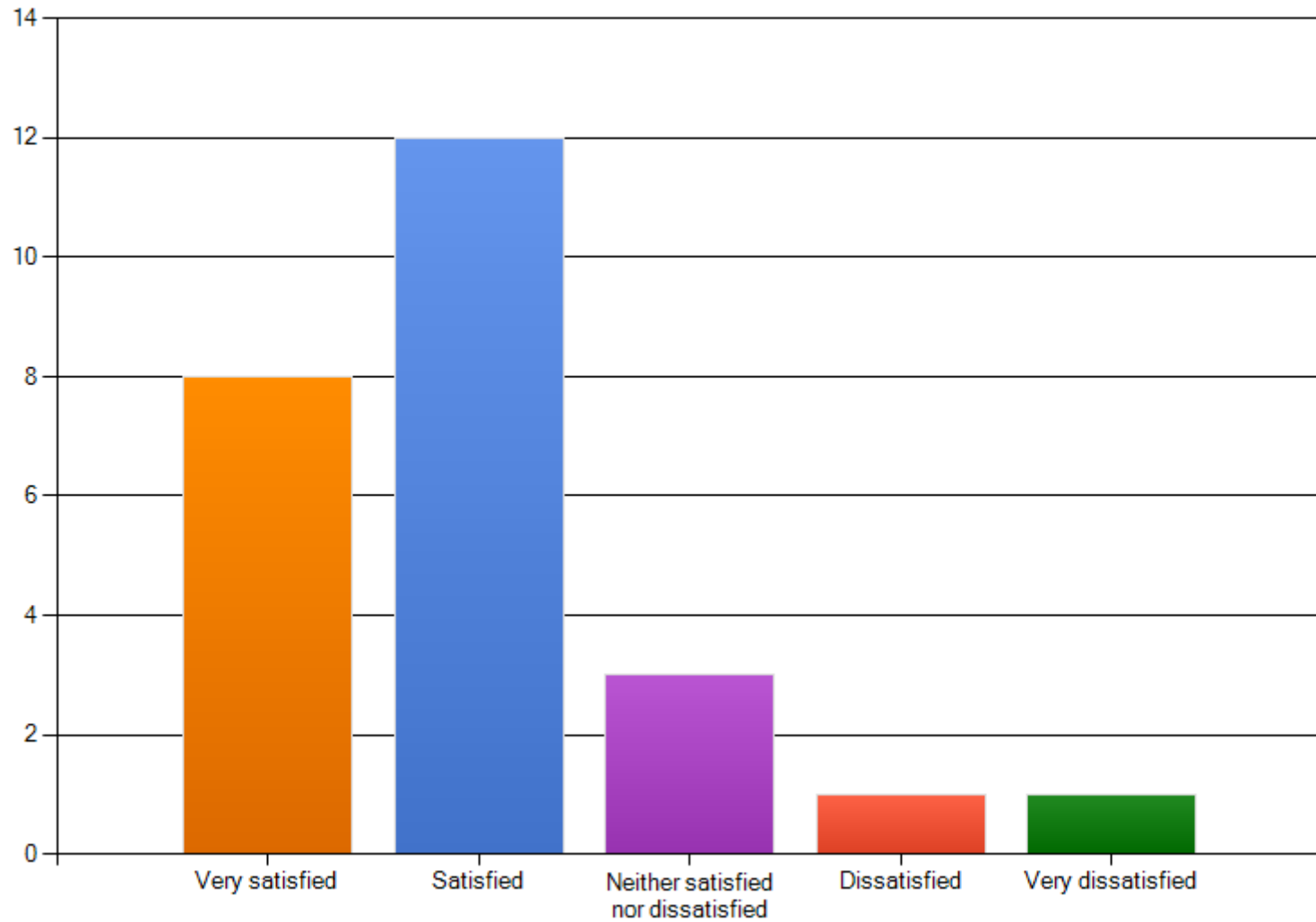
## Comments

- The final one was sent to me but I did not have time to compare it with my comments
- Never saw final documents
- Very few comments taken on board



# Review of documents

**The training sessions and/or material offered by the EMA to participate in the review**





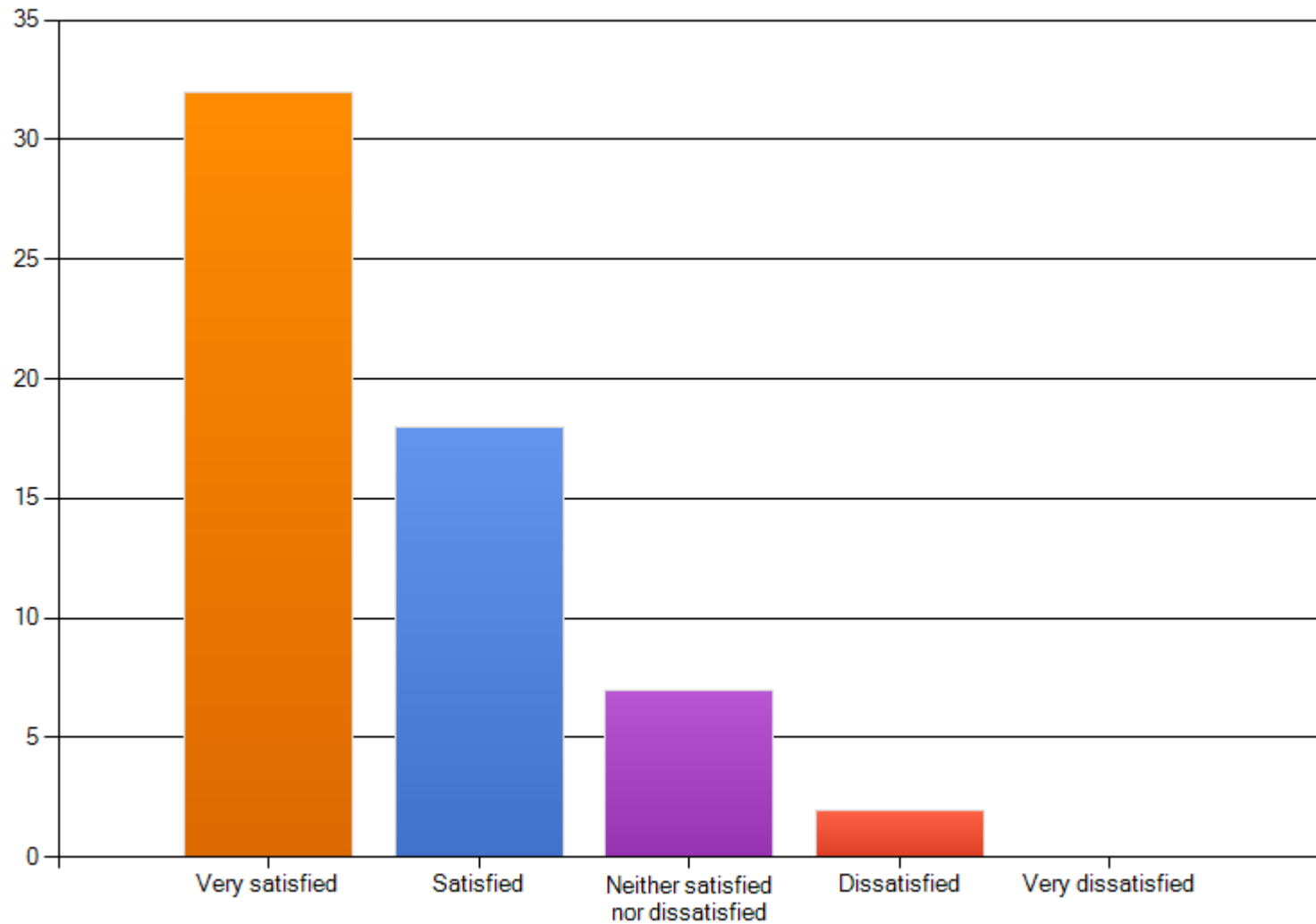
## Comments

- I think that there could more to help new reviewers - a 'reviewers help desk' or similar
- Did not participate
- I have had no training
- Too procedure oriented
- Not applicable I did not take part



# Logistics

Were you happy with the practical arrangements/facilities provided by the EMA





## Comments

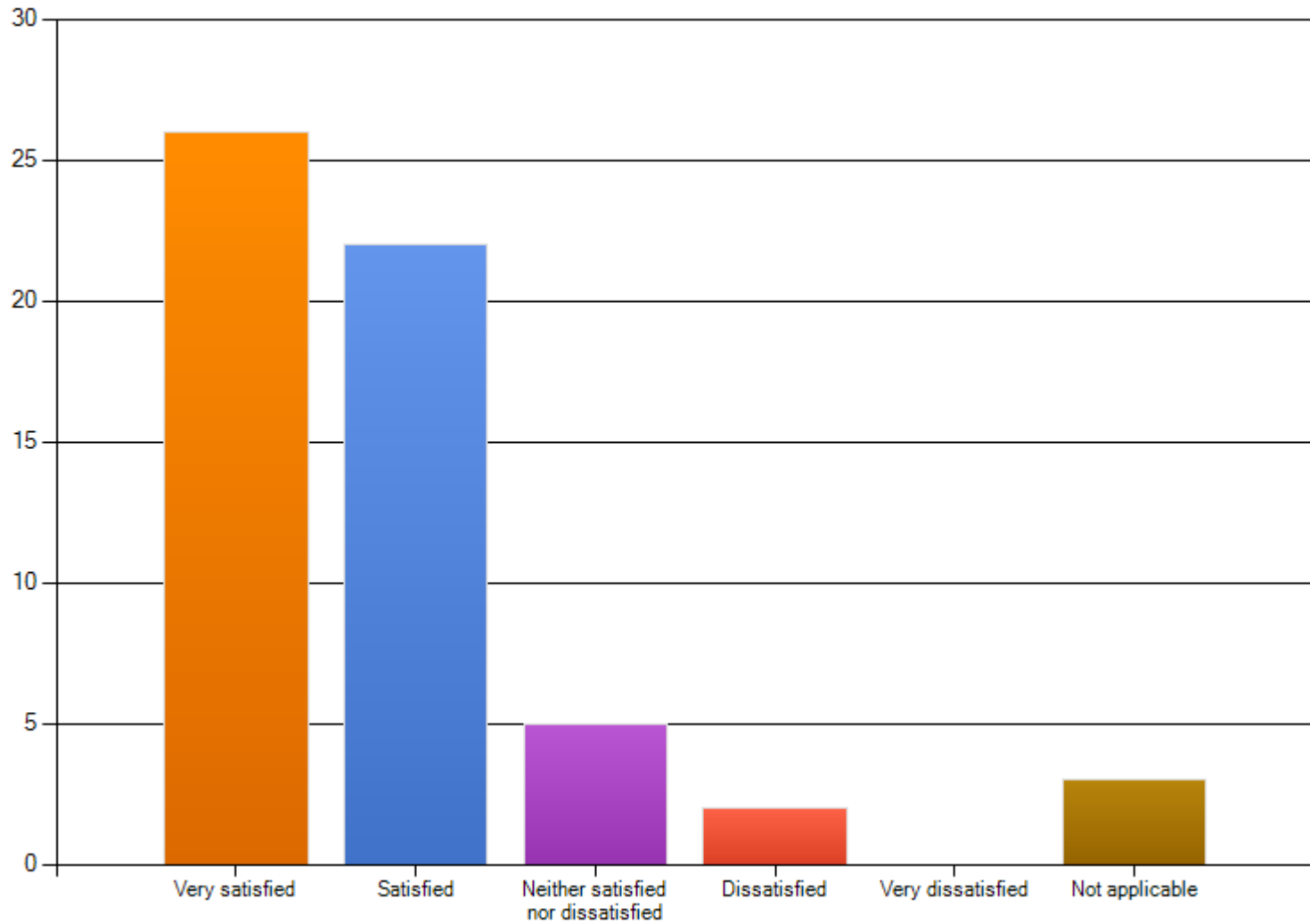
- But not yet received reimbursement (2 months)
- Excellent arrangements. Thank you
- Extremely helpful whilst I was unable to walk
- Cannot participate, must pay my own travels
- Very adequate last minute arrangements!
- Everything has been very good though I did not get all the info about the cashless system the first time
- The travel department is marvelous





# Logistics

Were you happy with the organisation of EMA meetings including the PCWP





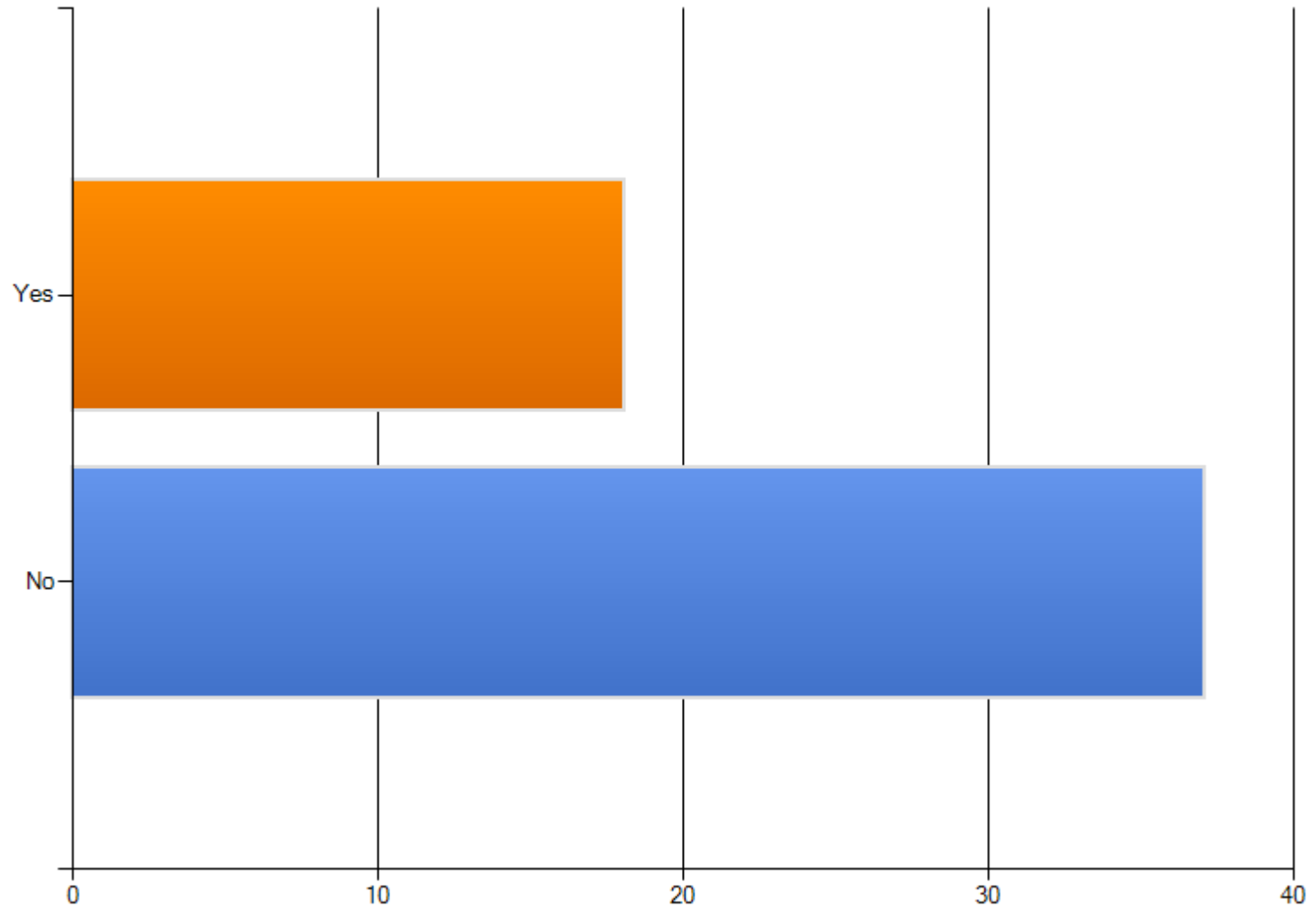
## Comments

- Documents are often available late. This could be better for it is often difficult to prepare well for meetings of the PCWP
- The documents are long and need careful studying - is it possible for the long documents to have an executive summary
- It lacks a document showing the whole procedure and steps toward commercialization of a drug
- The time schedule was not held and the last speakers had hardly any time to speak



# Logistics

**Did you receive extra financial support (i.e. double daily allowance)?**





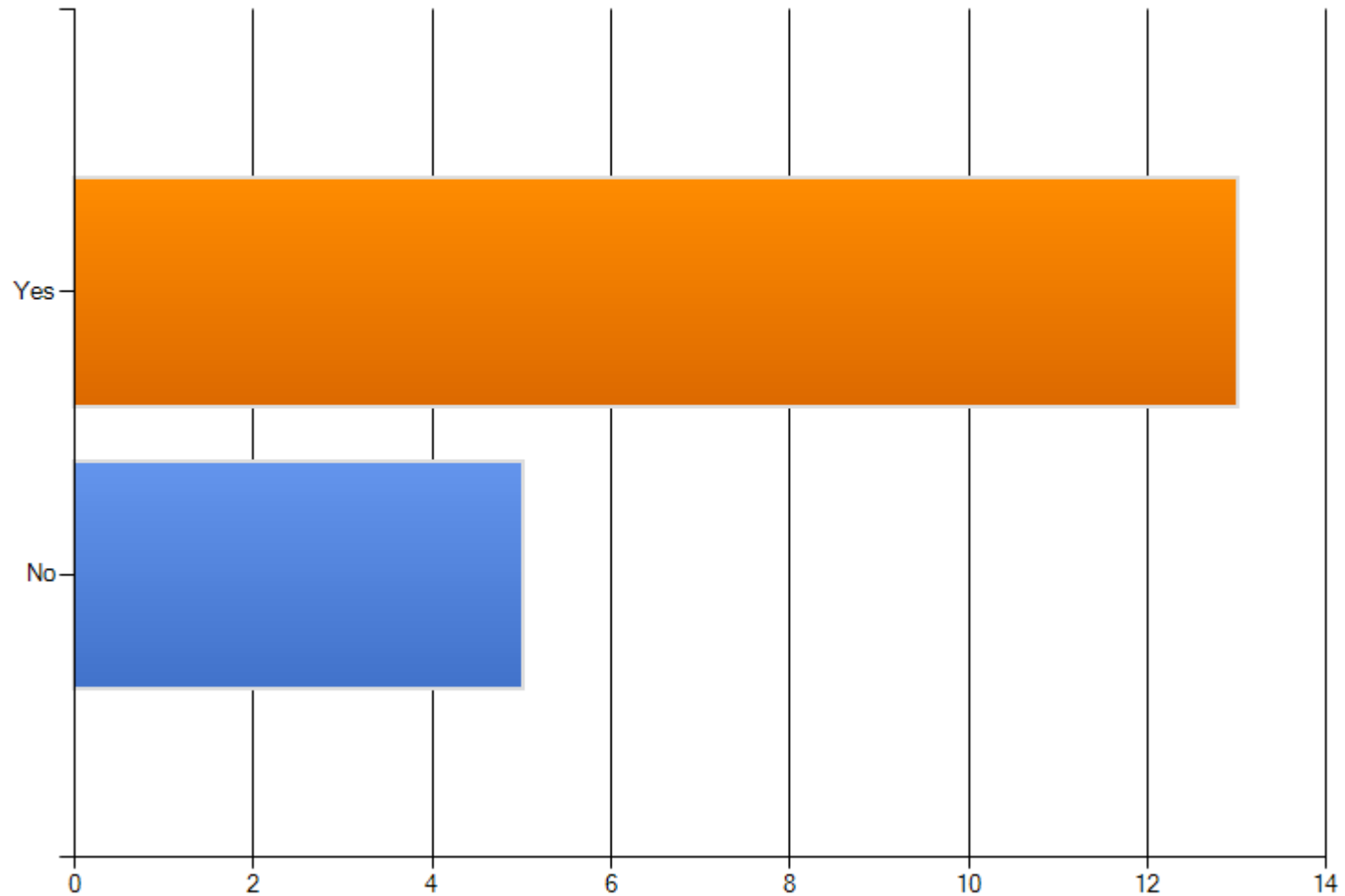
## Comments

- Could alternates when attending as sole representative of an organisation be reminded each meeting to apply
- Makes a difference to organisations with very few staff



# Logistics

**Did the extra allowance have an impact on whether you were able to participate in the EMA activities?**





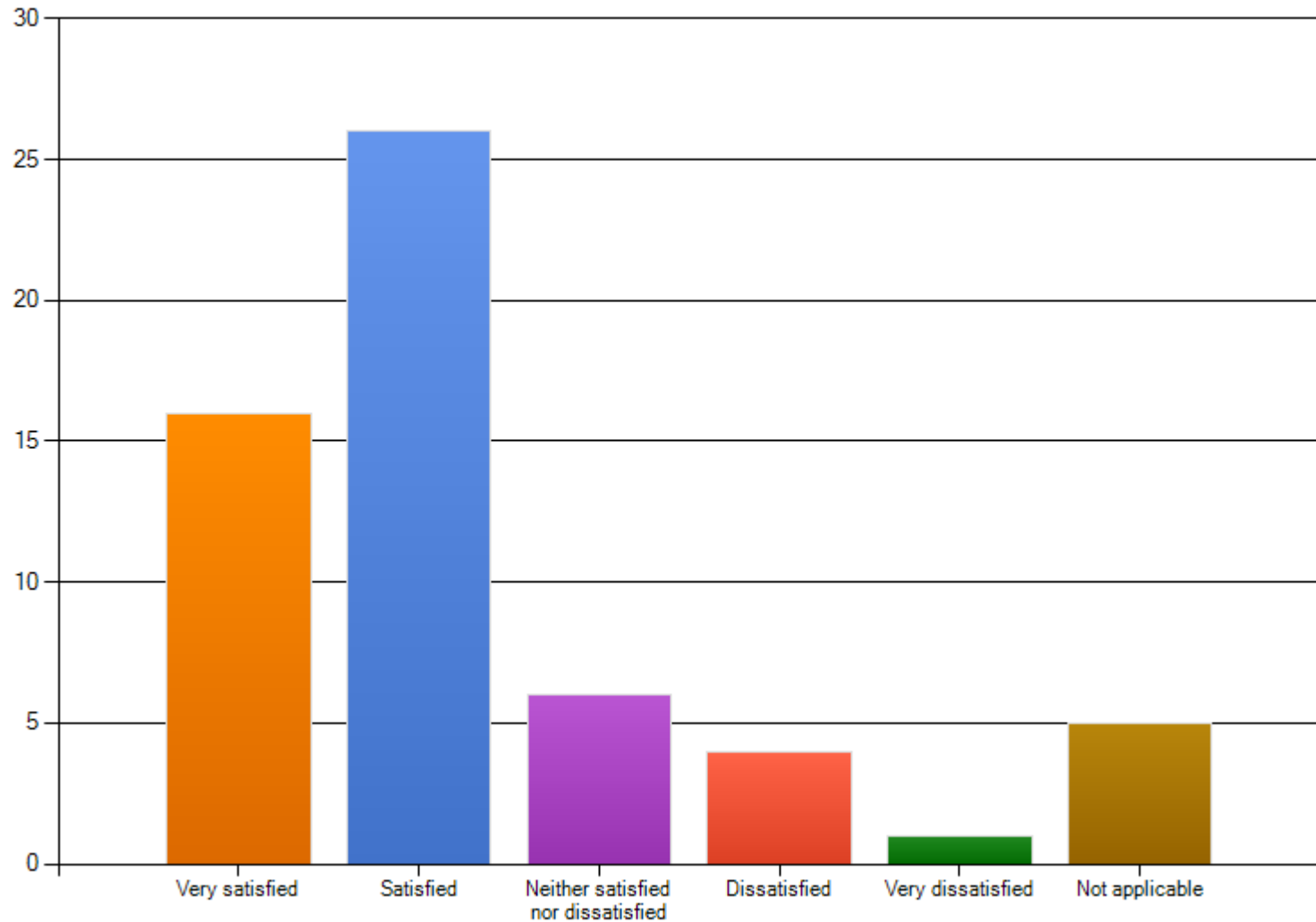
## Comments

- Not in my case. I am a volunteer. Yet I am happy with the extra allowance for there are so many additional costs when you are traveling
- It showed a willingness to understand the conditions of the patient reps
- I am self employed- this payment made by EMA made it possible for me to attend and not worry about my loss of income as you gave an allowance - thank you. A definite plus
- For my activities, I have to take days off at my regular work, which costs me money. The allowance helps to cope with the loss of salary (not completely)
- At least for voluntary based patient organisations the double allowance (for the day and the preparation day) should be in place otherwise the quality and even the possibility of meaningful participation is very difficult



# Logistics

**Are you satisfied with the overall level of financial support provided?**





## Comments

- I use my working time to act as a volunteer but of course reviews of PLs, etc I do on my leisure time
- It should be quicker reimbursement for people on low income or benefits
- The financial support is only for the time spent in meetings, not for the preparation time and the lack of compensation discourages professionally active patient representatives to take on more responsibilities and work
- We as patients representing patient groups undertake a lot of work as a volunteer and give of our time without payment. This payment from you was very welcome





## Comments

- Funding schemes from the EC should be set up to financially support patient representatives in this work. This will guarantee the quality of their work and make it sustainable
- As an unpaid volunteer, I have to subsidise additional costs myself
- The overall financial support to patient representatives, particularly the volunteers, is not enough to compensate for their loss of revenue/days off and makes it very difficult to identify volunteers in the various scientific committees for example
- Patient experts are not paid in contrast to other experts



## General comments/suggestions on interaction

- Over the past few years there has been genuine progress in actively involving PCOs and widening their roles, this will always take time given the complexities of EMA's role, plus the need to ensure PCOs are adequately trained to take part in EMA's affairs. There is a continuing need to regularly remind all EU patients orgs of the opportunities for involvement and where possible to encourage the national competent authorities to mirror the EMA approach when involving patient/consumer organisations
- Go on this way and let the PCWP come with proposals to make the involvement even more meaningful. The single fact that EMA has at the moment the best performance with regard to PCO involvement is a reason for satisfaction, but also a motivation to stay on top



## General comments/suggestions on interaction

- It is about partnerships and collaborative work!
- The two events I have attended we were made to feel very welcome - that is so important and our views were sought on various issues
- Time is an issue and short deadlines are not good for us
- I feel the EMA could do more to assist in the education and engagement of patients - to allow patients with appropriate credentials gain sufficient knowledge to represent patient views at higher and more influential levels



## General comments/suggestions on interaction

- EMA could be more involved on local level, especially east European countries
- There should be more personalized commitment to the person to really be committed!
- Maybe for some functions, more patient alternates should be foreseen. Patients unfortunately are confronted with health problems, meaning that they sometimes "drop out" because of their health
- The interaction between the EMA and patients and consumers is at an early stage; there is a long way to go on either side



## General comments/suggestions on interaction

- Much more consumer consultation is required before products are discontinued
- I believe EMA really wants to involve patients but because of complex procedures and limited time and meeting schedules it's very hard to really present a patient's perspective in the whole process. All people involved were very open and ready to help but still it was hard to figure out what the precise process would involve and how and when we could intervene and express our point of view
- The idea to involve relevant organisations and patients-consumers is very important and I hope I will have more opportunity to attend similar trainings in the future, and learn more about your excellent work



## General comments/suggestions on interaction

- I know the work is in progress but it's urgent that public / transparent criteria with clear DoI's is in place for individual patients, the organizations and also for clinicians and researchers
- EMA is currently the best of EU institutions in providing support in connection of meetings. Regarding reviews, it is still totally voluntary
- Speed up payment process which takes many months
- Information and communication towards "lay people" is necessary, the Agency seems far away