EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Results from the questionnaire to PDCO members

- ***Involvement of children, adolescents, parents/carers or legal representatives in the PDCO activities***
- ***Strengthening the participation of members representing patients' organisations in the PDCO***

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An agency of the European Union

Introduction

Recommendations from concept paper on the involvement of children and young people at the PDCO (2012) *:

- Define a framework of interactions between EMA, PDCO, children and/or adolescents and patients' organisations;
- Define the expectations and role of children and adolescents to support PDCO activities;
- Develop clear criteria on which situations need the consultation of children, adolescents and patients' organisations.

6th annual Enpr-EMA workshop (June 2014):

- Topic on involvement of children and young people in clinical research: it is important to engage children at every feasible stage of the research activities.

* http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/09/WC500132555.pdf

Structure of questionnaire

1. **Involvement of children/adolescents in the activities of PDCO**

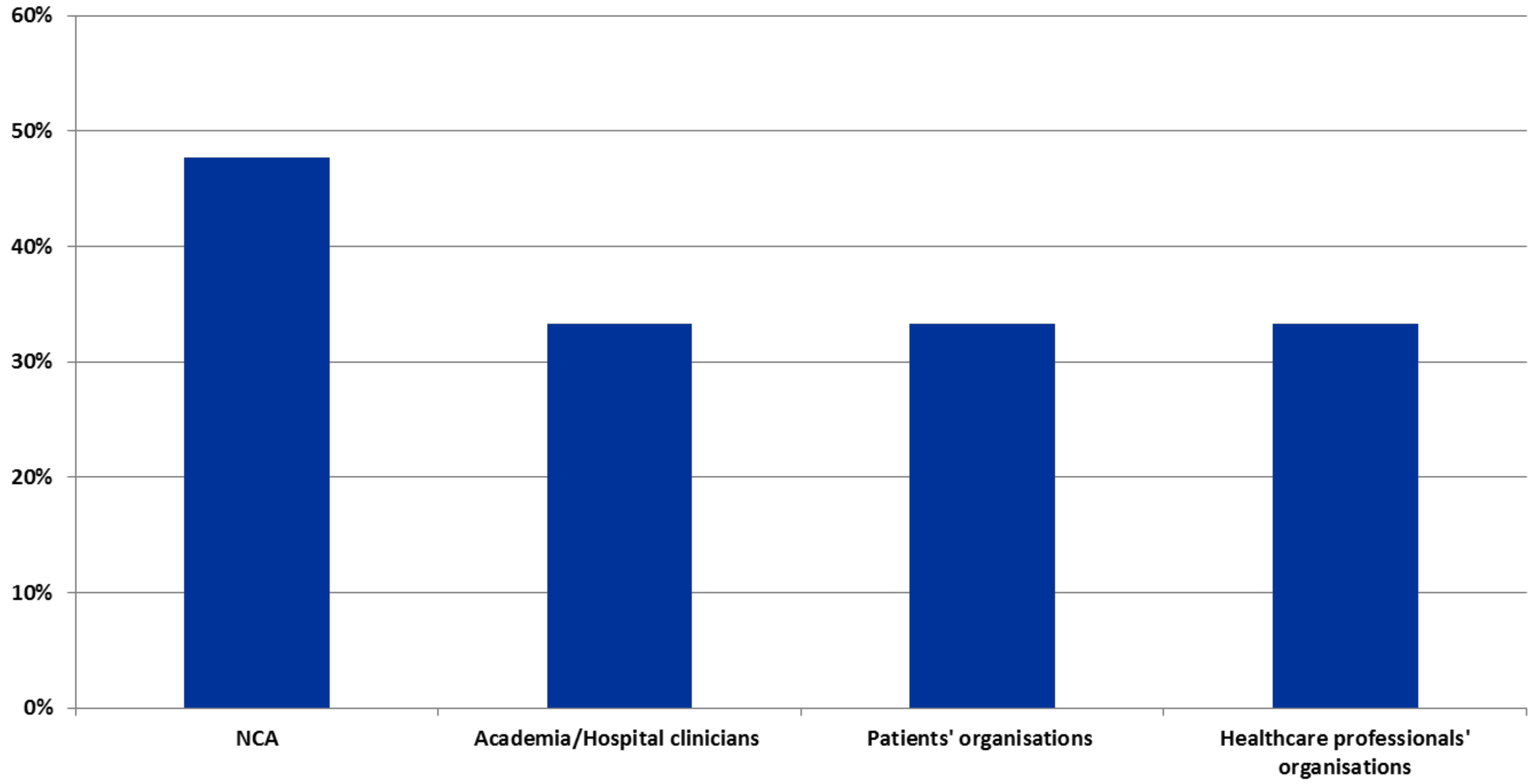
2. **Involvement of parents/carers or legal representatives in the activities of PDCO**

3. **Strengthening the participation of members representing patients' organisations in the activities of PDCO**

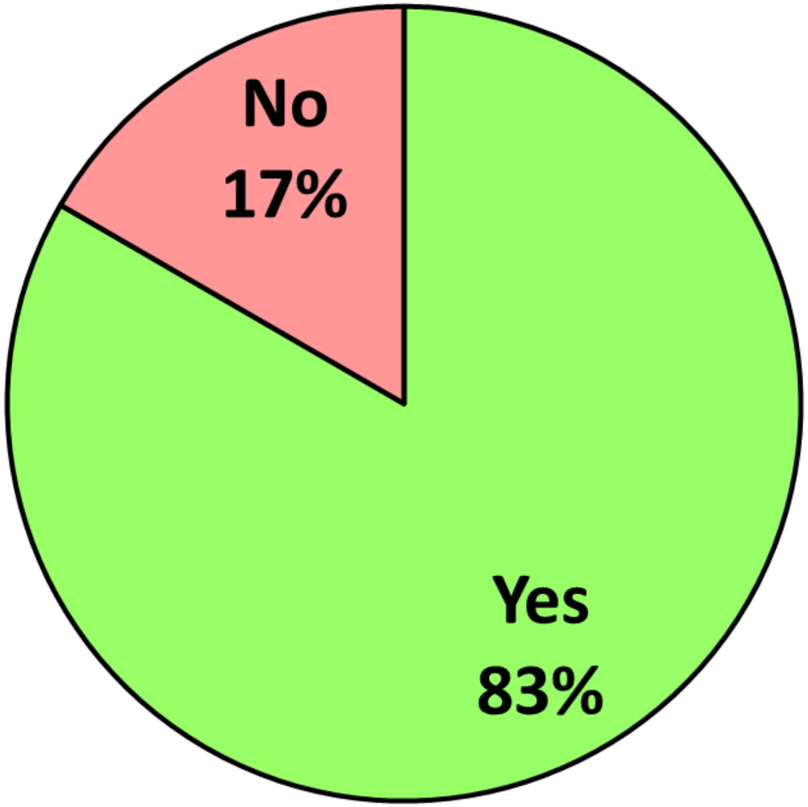
Results

Response rate

30 of 70 members **(43%)** responded to the questionnaire



Do you see a benefit to involve children and/or adolescents in the activities of the PDCO?



Members’ comments on involvement of children

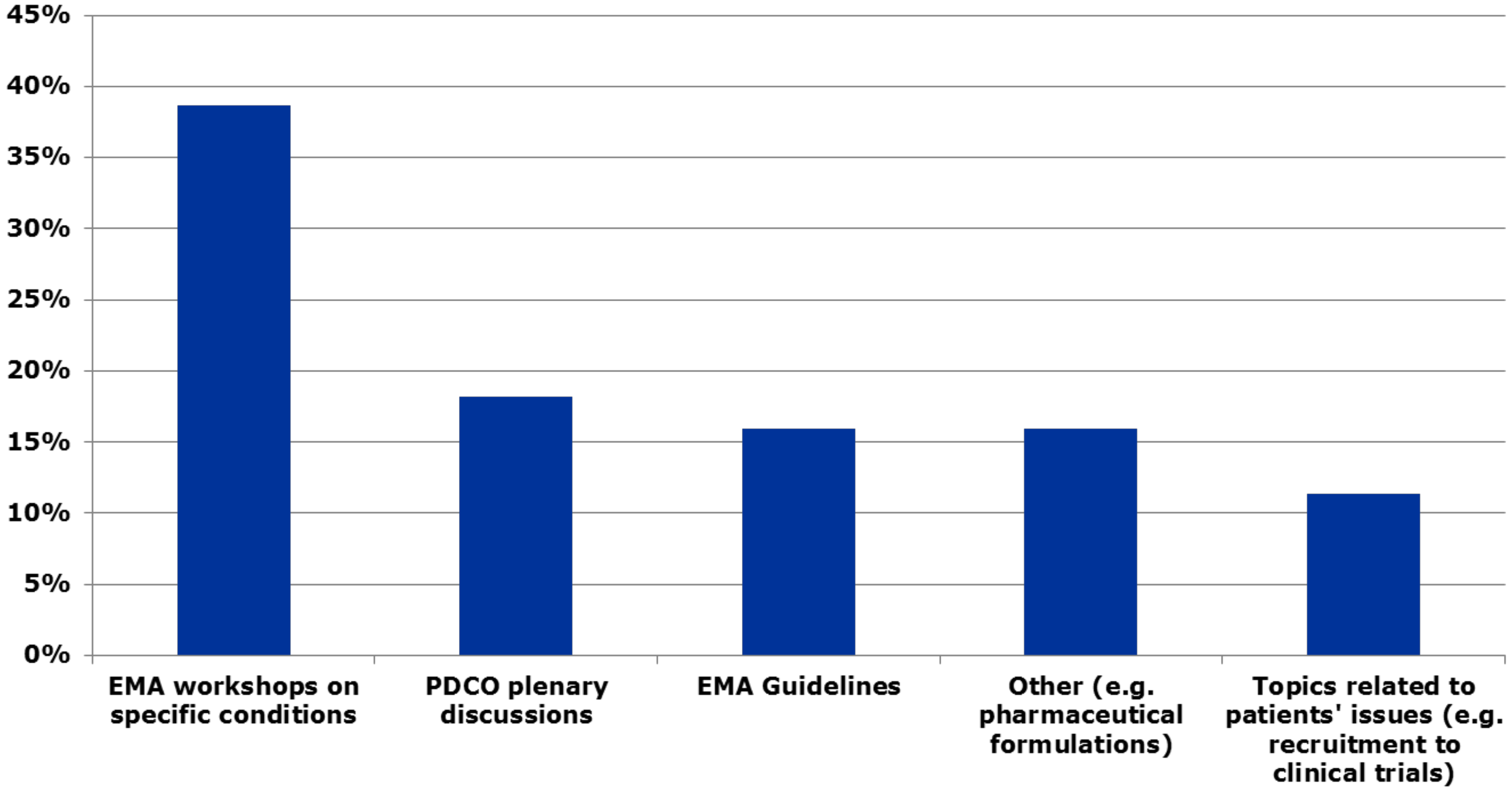
No

- “Not the right innovation”
- “It is the role of patients’ organisations, not children”
- “For practical reasons, this is too difficult”
- “Children are not interested and don’t know about the PDCO”
- “Involvement doesn’t necessary mean benefit”

Yes

- ”Very good to have an established working group to refer questions to if PDCO needs to”
- ”Involvement is needed to have a better understanding of how the children cope with their disease”
- ”Different children depending on the type of questions”

For which specific situations would you see a benefit to involve children and/or adolescents in the activities of the PDCO?

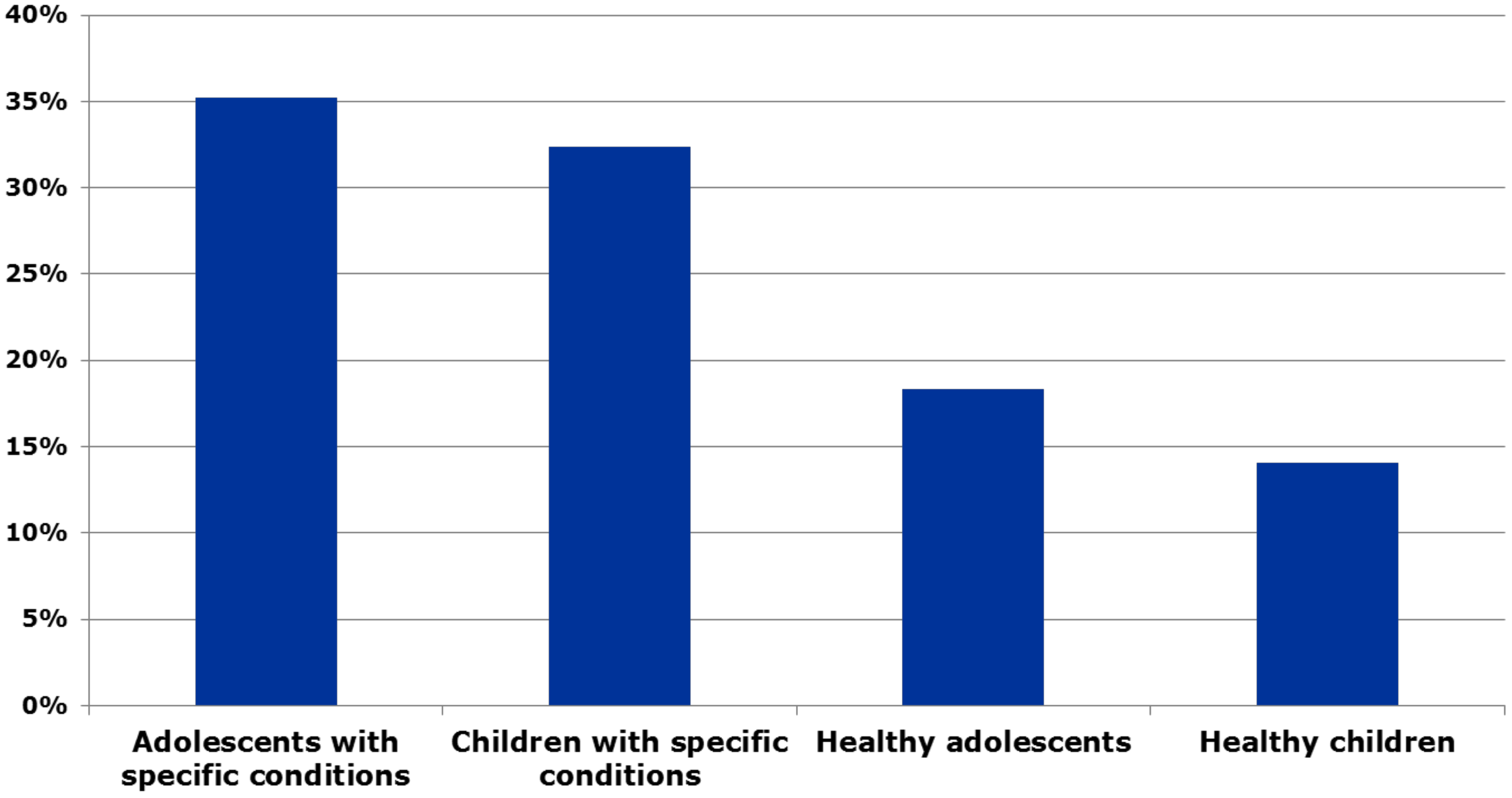


Relevant added comments linked to the involvement of children

<u>Members' comments:</u>

- *"Need for clearly defined questions for the children who are participating".*
- *"Make the children active participants and not 'subjects' in clinical trials".*
- *"Established groups of children that PDCO can ask trials-specific questions".*
- *"Topic-driven focus groups rather than on specific products or procedures. Topics should focus on the burden of therapy, rather than the burden of the disease, which we have no direct control over".*

What should be the target paediatric population?

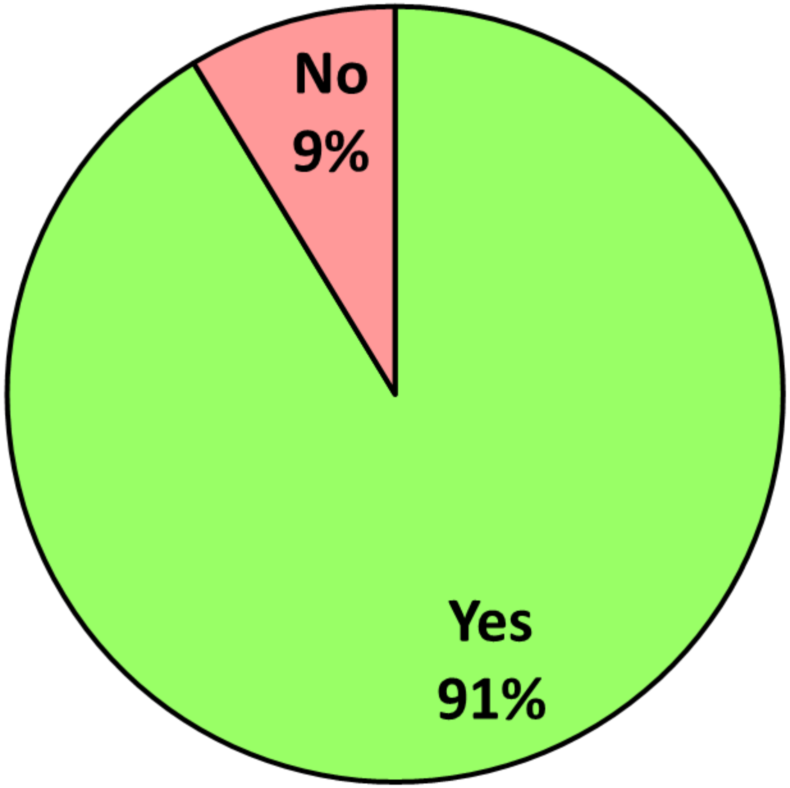


How often children or adolescents should be involved

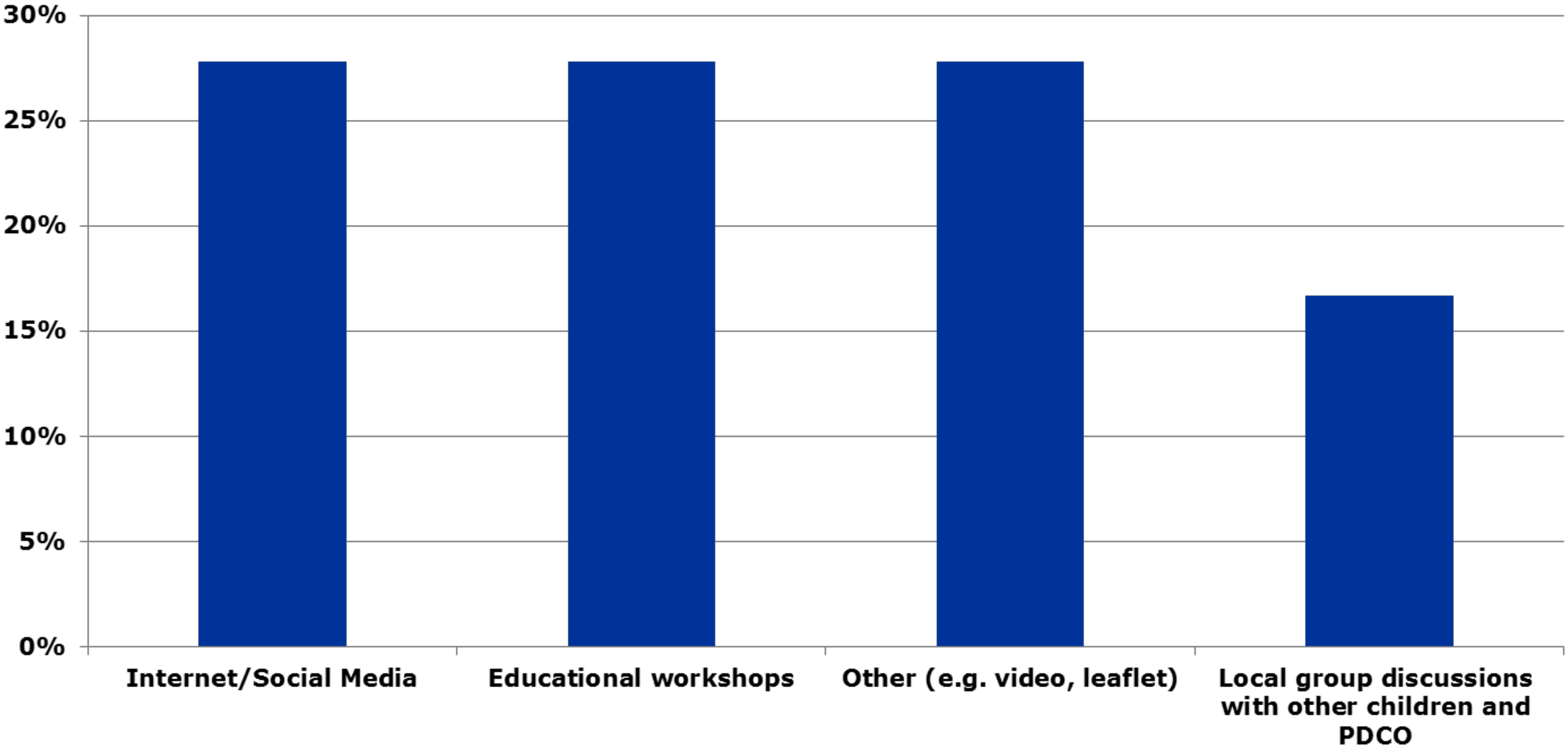
Trend response:

- *On a limited basis: “circa twice yearly according to school holiday time”.*

Do you see a need to involve, along with children and/or adolescents, parents, carers or legal representatives in the activities of the PDCO?

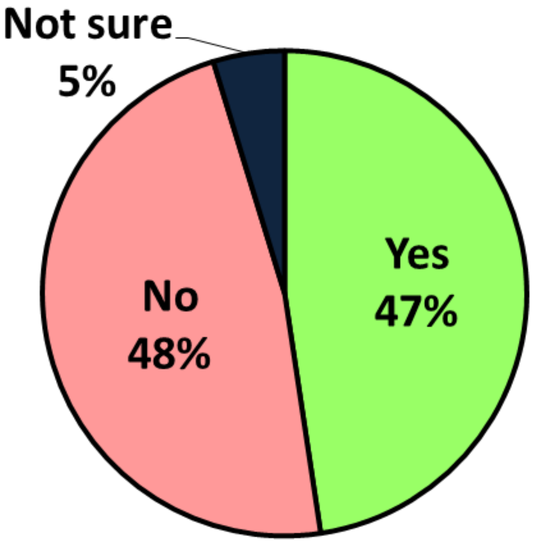


How could keen children and/or adolescents (and parents, carers or legal representatives) be best trained/informed so as to be prepared for their involvement in the PDCO activities?



Do you think it may be beneficial to set up a small PDCO Working Group whose primary role would be to further define the scope and specific objectives of the involvement of children and/or adolescents (and parents, carers or legal representatives) in the activities of the PDCO?

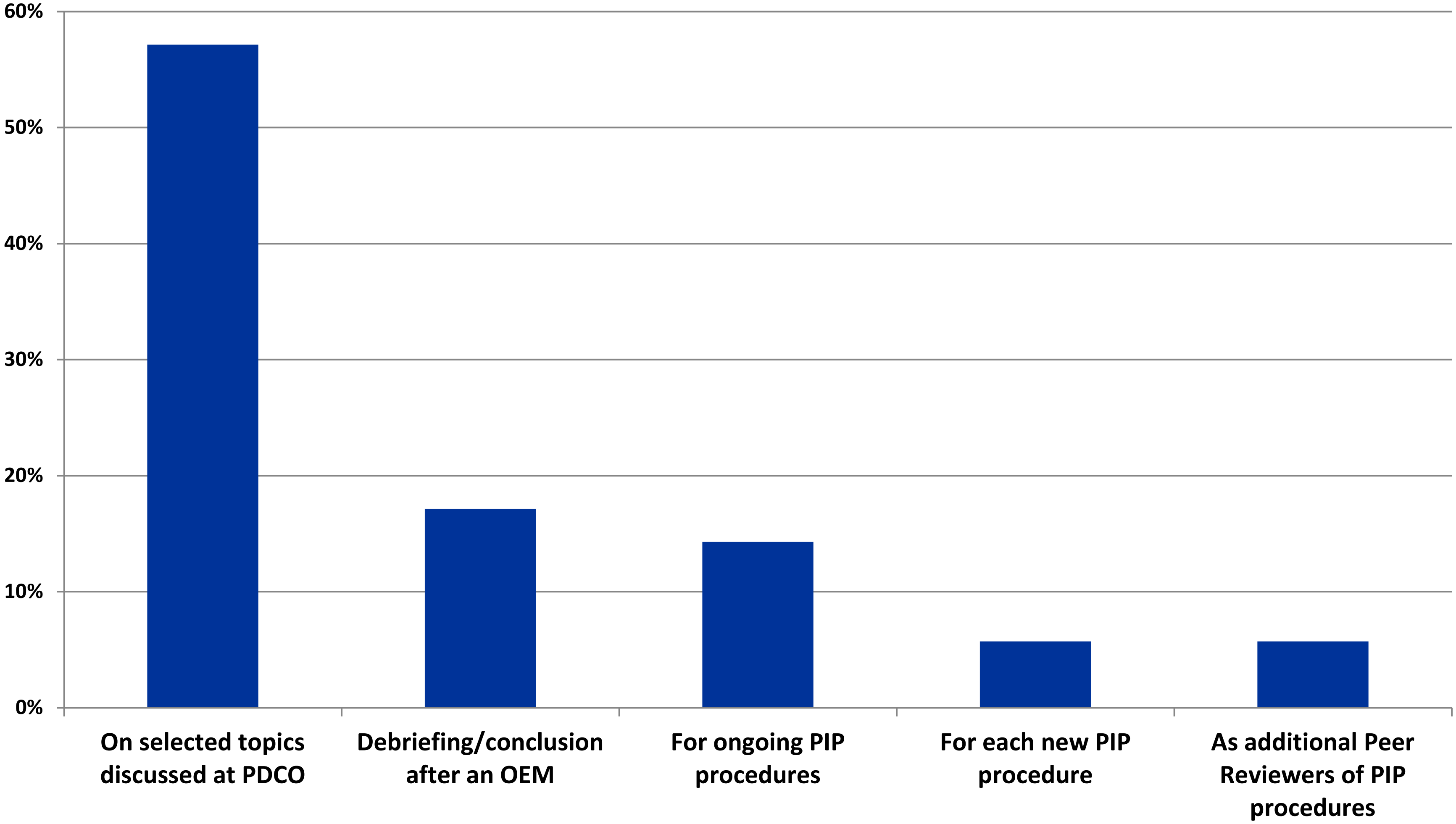
Beneficial Yes/No



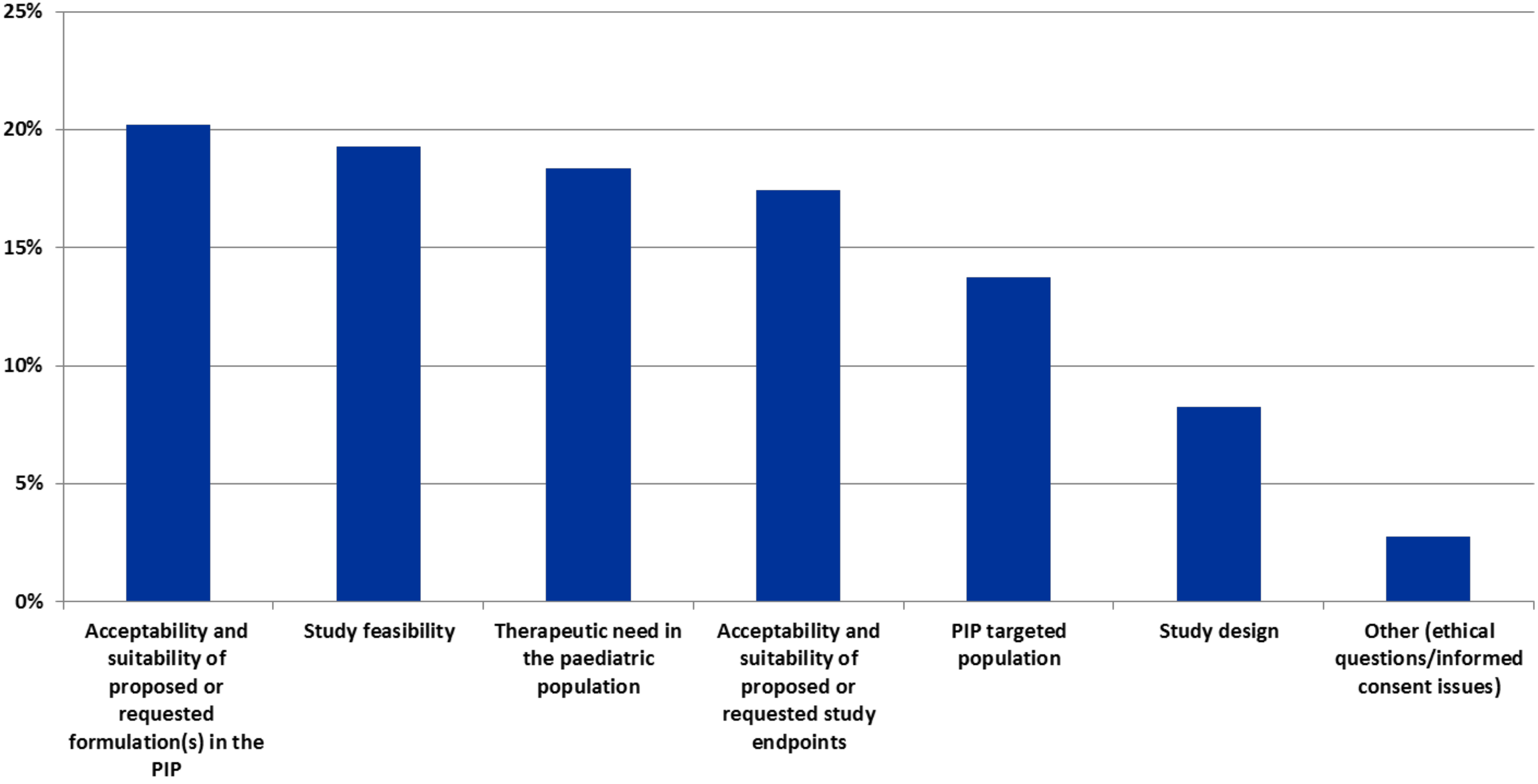
→ **If yes, would you like to be a member of this group?**

1/3 (10 responders) wish to become members of the WG

When do you think a systematic feedback from patients' organisations would be required?



What would be the issues the members representing patients' organisations attending the PDCO could provide systematic input on?



Challenges for involving children and adolescents in the PDCO activities

- **Language barrier** (issue with non-English speaking children);
- Need for **adapted training** and adjusted terminology so that information can be easily understood by children and adolescents;
- Unknown access to pool of patients in some EU countries;
- Need to define **clear and specific questions** to children and adolescents;
- Travel to EMA if participation in person / Avoid missing school;
- Priority in terms of **therapeutic areas** to be looked at first (high variation in responses among PDCO members);
- To define **minimum age** for involvement (high variation in responses among PDCO members).

Next steps

- Presentation of the questionnaire outcomes to the PDCO plenary in December;
- To set up a **small PDCO WG** to better define the scope and objectives of the involvement of children/adolescents and their parents/carers or legal representatives;
- To circulate **questionnaires** to children on views in taking medicines and views in taking part in clinical trials;
- To raise awareness on the **need for clinical trials in children**, and develop better information and communication on clinical trials to increase children participation (? create a video or leaflet);
- To set up, via Enpr-EMA, a **virtual EU network/platform** of young people to input into the design and delivery of research in children.

Any questions ?